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UNCERTAIN RETURNS

The Multimillion Dollar Market in Reimported Pharmaceuticals

A STAFF REPORT

PREPARED FOR THE USE OF THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

JULY 1986

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of the
Committee on Energy and Commerce
Washington, DC 20515

July 9, 1986

LETTER OF TRANSMITTAL

TO MEMBERS OF THE COMMITTEE ON ENERGY AND COMMERCE:

It is my pleasure to forward to you a report by the staff of the Subcommittee on Oversight and Investigations entitled, "Uncertain Returns: The Multimillion Dollar Market in Reimported Pharmaceuticals." This report presents a comprehensive analysis of the sale and resale of legend drugs produced by U.S. manufacturers, sold abroad and then reimported into this country. These medicines may pose a serious threat to the health and safety of American consumers. Most of the transactions discussed in the report appear to be schemes to acquire drugs at prices below those which can be obtained in the United States.

H.R. 4920, the Prescription Drug Marketing Act of 1986, introduced by Mr. Broyhill, myself, and nine other Members of the Subcommittee on Oversight and Investigations, would remove this risk to the American consumer by banning such reimports, except under strictly limited circumstances, and by making it a felony to deal in those reimported drugs that may be reentered illegally.

Once you have read this report, I am certain that you will concur in the pressing need for this legislation.

Sincerely,

John D. Dingell
Chairman
Subcommittee on
Oversight and Investigations

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UNCERTAIN RETURNS: THE MULTIMILLION DOLLAR MARKET IN REIMPORTED PHARMACEUTICALS

I. INTRODUCTION

Over a six-month period between September 1985 and March 1986, over $10 million worth of pharmaceuticals reentered the United States. The entry documents have been abstracted and the abstracts are incorporated in this report.

The drugs came from all over the world. Two of the 189 entries involved counterfeit labeling and packaging. In at least two instances, phony invoices were apparently supplied to the Food and Drug Administration (FDA).

The drugs came from twenty-nine foreign countries. Conditions of storage were usually unknown. Many traveled by ocean freight from some of the hottest climates on the planet.

The FDA subjected the drugs to laboratory analysis only rarely. It is probable that those released have been distributed to retail pharmacies throughout the United States.

During the summer of 1985, the Subcommittee staff, at the direction of Chairman Dingell, began an intensive examination of pharmaceuticals entering the United States as "American Goods Returned," a tariff classification that designates U.S.-produced goods that have been exported and are then reimported. This inquiry, part of a larger, on-going investigation into prescription drug diversion and counterfeiting, was triggered by the discovery that counterfeit Ovulen 21 birth control pills had entered the United States declared as American Goods Returned.

Pharmaceuticals must be labeled in conformance with FDA requirements and manufactured in an FDA-approved facility in order to be sold in this country. Thus, counterfeits from abroad, if declared to the Customs Service at all, are typically declared as products of U.S. origin which were exported and then reimported.

All American Goods Returned enter the United

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States duty-free, and returned pharmaceuticals had long been given cursory treatment by overworked Customs and FDA officials. The Customs Service routinely "by-passed" such entries -- a term which means that the shipments were not physically inspected and the accompanying entry documents received only cursory review -- because they yielded no revenue.

FDA inspectors, who are responsible for safety concerns, also assigned such entries low priority, apparently because of their U.S. origin. One Customs Service inspector in a very busy port told of being entrusted with an FDA "may proceed" stamp and instructed to approve the entry of all returned pharmaceuticals.

The discovery of counterfeit Ovulen and the attendant publicity produced a heightened concern about reimported pharmaceuticals among at least some Customs and FDA field personnel. One alert Customs import specialist at JFK Airport in New York recalled an Ovulen 21 entry she had seen in a spot check of by-passed entries and was able to interdict a shipment of counterfeits from Panama to Quality King Distributors, Inc., a Long Island, New York dealer in diverted drugs. In Boston, Massachusetts, a Customs inspector working with an import specialist began detaining such shipments pending FDA investigations well before the Customs Headquarters issued instructions to the ports.

In a handful of instances between November 1984 and August 1985, pharmaceutical manufacturers reported that FDA compliance officers called to verify lot numbers of reimported pharmaceuticals prior to their release. These efforts by FDA personnel appeared to be sporadic, lacking specific direction and the exception rather than the rule in dealing with reimports.

Following publication of the initial staff report on the larger investigation,1 and the revelations of

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1 "Prescription Drug Diversion and the American Consumer," Staff Report by the Subcommittee on
(Footnote continued)

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the first forty-six criminal informations filed by the United States Attorney for the Northern District of Georgia,[2] Chairman Dingell asked the Customs Service and the FDA to detain all reimported pharmaceuticals until they could be tested for safety and efficacy.[3] Commissioner William von Raab of the Customs Service responded quickly and positively to the request. However, Commissioner Frank Young of the FDA, the agency with principal responsibility, expressed serious concern regarding the type of testing required and its possible cost. Because little attention had been paid to reimported pharmaceuticals, neither agency could ascertain the number of entries which would require this scrutiny.

After some discussion, FDA agreed to implement certain procedures on an experimental basis. The Subcommittee's understanding of the agreed-upon procedures were described in an August 29, 1985 letter from Chairman Dingell to Commissioner Young, as follows:[4]

> As I understand the proposed system, Customs will halt the <u>physical</u> entry of all pharmaceuticals marked "American Goods Returned" until the FDA approves their release into domestic commerce. Surety bonds will not suffice for entry.
>
> The FDA will insist on documentary proof of the custody of pharmaceuticals of all parties back to the original manufacturer. Further,

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1(continued)
Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, 99th Cong., 1st Sess., Committee Print 99-R (hereinafter cited as "Committee Print 99-R").

2 "Prescription Drug Diversion and Counterfeiting--Part 1," Hearings before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, 99th Cong., 1st Sess., Serial No.
(Footnote continued)

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FDA will physically inspect the packaging of each shipment. If either the documentation or physical inspection gives rise to any suspicion that the pharmaceuticals may be counterfeit, outdated, or otherwise adulterated, the FDA will insist that the importer provide them with an analysis from an FDA certified laboratory that confirms that the drugs are safe and efficacious.

Only after the FDA is convinced that the pharmaceuticals are safe will Customs be notified that the merchandise may be released into the commerce of the United States. Additionally, the FDA will continue its 'program of routinely sampling and analyzing certain drug imports, regardless of country of origin.'

Chairman Dingell's letter continued:

Because of the experimental nature of this program and the serious threat to the public health involved with these entries, the Subcommittee intends to monitor its implementation very carefully. Accordingly, you are requested to provide the Subcommittee with copies of all documents associated with all attempted entries into the commerce of the United States of pharmaceuticals designated as "American Goods Returned" for the period September 1, 1985 to September 30, 1985. These include, but are not limited to, the Customs and the FDA entry documents, all written correspondence and notes of telephonic communications with importers, manufacturers or other parties, documentation of custody and

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2(continued)
99-61 (hereinafter cited as "Hearings, 99-61"), August 6, 1985, Testimony of Richard Allen.

3 See Id., pp. 40-45 for letters and responses.

4 The letter is retained in the Subcommittee files.

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laboratory analysis associated with each entry.

FDA promised to provide such documents for all pharmaceuticals reimported after September 15, 1986. Chairman Dingell subsequently extended his request to include documents relating to all such reimports through April 15, 1986. To date, the Subcommitee has received documents covering pharmaceuticals reimported through March 31, 1986.

These documents have been analyzed and abstracted. The abstracts are appended to this report.[5] They form the basis for most of the narrative contained in this report. It is therefore important to understand the limitations on the data employed.

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5 It should be noted that these documents were provided by FDA pursuant to a request from the Chairman of a Committee of competent jurisdiction of the United States House of Representatives.

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II. CAVEATS: THE SCOPE OF THE DATA

Publicity surrounding three events in the summer of 1985 undoubtedly drastically reduced the volume of reimportations before the Subcommittee received any documents. In July 1985, the Subcommittee staff report was released. In August 1985, the U.S. Attorney first announced the criminal prosecutions of dealers in diverted drugs. Finally, the Subcommittee issued a press release announcing the agreement with the Customs Service and FDA regarding the new reentry examination procedures for pharmaceuticals.[6] One major wholesaler who was purchasing $8 million worth of diverted drugs per year virtually ceased dealing in imports before September 15, 1985.[7] The Customs broker for another diverter who received ten shipments through the Port of Boston, Massachusetts over the examination period informed FDA Boston, "Consignee has had 30 to 40 shipments through Boston in the last eighteen (18) months."[8]

Further, as Table I indicates, once FDA began to insist on a paper trail dating back to the original U.S. manufacturer, the number of shipments dropped off even further.[9]

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6 Each of these events received national publicity and was covered by the extensive trade press of the pharmaceutical industry.

7 Staff interview with Marvin Sandler.

8 FDA Sample # 579072. The appended abstracts are ordered by ascending FDA Sample Number. All cites to the appended abstracts will be by FDA Sample Number.

9 Obviously, at least some FDA field offices supplied documents for all reimports which had not been released when the September 6, 1985 import alert was issued by FDA Headquarters. There was only one entry for July, ten entries for August, and numerous entries for pharmaceuticals which physically arrived in the U.S. during the period September 1-14, 1985. It should be assumed that the data for July and August is very incomplete, but that the September data is

(Footnote continued)

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9(continued)
only minimally understated. Further, in Subcommittee staff review of the Boston FDA files, one entry for March 1986 was discovered that had not been forwarded to FDA Headquarters. Staff examination of the Boston files showed less than five entries for all of April, May and most of June 1986; hence, it may be assumed that the decline continues.

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TABLE I

AMERICAN PHARMACEUTICAL GOODS RETURNED

DATE	ENTERED VALUE
July & August 1985	$1.0 million
September 1985	$2.5 million
October 1985	$1.0 million
November 1985	$1.5 million
December 1985	$1.6 million
January 1986	$1.7 million
February 1986	$0.8 million
March 1986	$0.1 million

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The shipment information is likely to be incomplete for several other reasons as well. The Customs Service continues to by-pass most American Goods Returned. By-passed entries are examined only by low-level Customs clerks for duty and census purposes. If there is no duty associated with a by-passed entry, it will not be reviewed. The Customs broker knows to attach the FDA Form 701 which triggers the intense examination only if the goods are invoiced as pharmaceuticals. Human error and deliberate fraud can result in no examination.

Further, the Customs Service inspects only one-half of one percent of all containerized freight entering the United States. Thus, smuggling remains another source of entry which would elude detection.

With minor exceptions, the Subcommittee has not compiled information on domestic "daisy chains." Diverted drugs undoubtedly pass through at least as many hands after they have been reimported as they did overseas. Both here and abroad, the basic principle of diversion trade is "never reveal your source to your customer." The paper trails that were provided FDA were only available because FDA would not release the goods without them. No equivalent document trail exists for the goods once they enter domestic commerce.10

There are several other important restrictions on the data. Most importantly, as of this writing, FDA has not provided the Subcommittee with all documents in each file. Full compliance is expected before release of the report. The abstract is based on an examination of all documents obtained by FDA only in the case of the Boston region. In many cases, only the initial FDA Form 701 and the invoice pertaining to the import itself were forwarded to the Subcommittee.

As a result of the gaps in the documents provided to the Subcommittee, the abstracts provide an incomplete picture of the actual work of the FDA. For

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10 Such documentation would be required under a provision of H.R. 4820, the Prescription Drug Marketing Act of 1986.

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example, FDA provided the Subcommittee with a computer list of the status of each entry as of March 31, 1986. When complete chains of custody were provided FDA, but not all documents reached the Subcommittee files, the abstract would reflect FDA release based on incomplete documentation.

Similarly, Customs brokers are infamous for errors on the entry documents. Without supporting documentation, such basic information as the port of lading (export port) and port of entry (import port), declared value, and even the importer of record can be mistaken. Particular care should be taken in interpreting those abstracts which indicate a scanty document base. For aggregation purposes in the tables presented throughout this report, these caveats had to be ignored.

Finally, it should be noted that the "value" or "price" data is particularly unreliable for a number of reasons. First, the entry value reported to the Customs Service is not always accurate. Because no duty is involved, this is particularly likely to occur on entries claimed to be American Goods Returned.

Even when invoices dating back to the original export sale were provided, the importer usually removed price data from all but the final invoice. This data is not required by FDA. In the case of multiple medications on an invoice, itemized price data was often removed. No attempt was made to abstract this data, but some information was included in the "Notes" accompanying the abstracts.

In a reverse situation, the FDA documentation often picked up over-the-counter drugs and even health and beauty aid shipments. While the Subcommittee's investigation to date has centered on prescription medications only, it may be extended. Therefore, all entry data provided by FDA is included, except those involving returns to the original manufacturers. The latter entries are of no interest because the goods do not enter the commerce of the United States.

The entry values vary widely. In at least some cases, the exporter of record and the U.S. importer may be related parties, and thus, the transactions are not "arms-length," and the invoice price could be established for tax or other purposes. Information is

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closely guarded, hence, it is not surprising that an exporter of diverted goods is rarely found to sell to more than one U.S. importer. This means that competitive prices are not the norm.

Nor can it be assumed that the entry value reflects a calculable mark-up on the export price originally charged by the manufacturer when the goods left the United States. Overseas sales by U.S. pharmaceutical manufacturers can be at widely varying prices. The marginal cost of pharmaceuticals is minimal. Most U.S. manufacturers apparently capture the high research, development and marketing costs in this country. Sales to Eastern European countries are often through a single buyer, the state trading company. Sales to developing countries without patent protection must compete with so-called local generics.11 Other foreign sales are sometimes made either directly or under the auspices of the foreign government or when prices are mandated by that government. Thus, the original export price can vary widely and often may be some fraction of the average wholesale price (AWP) in the United States.

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11 See "Unfair Foreign Trade Practices: Selected Problems in Five Far East Countries," Staff Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, 99th Cong., 2nd Sess., Committee Print 99-CC (hereinafter cited as "Committee Print 99-CC").

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III. THE U.S. IMPORTERS OF DIVERTED PHARMACEUTICALS

As the Subcommittee noted in its April 1986 report,[12] diverted pharmaceuticals come from both legal and illegal sources. To date, the U.S. Attorney in Atlanta has obtained seventy-seven guilty pleas to charges of mail fraud, wire fraud, misbranding and adulteration. To the extent that the transactions discussed in this report involved fraudulently obtained goods, they may be violations of criminal statutes. However, it cannot be assumed that any individual importation involves criminal culpability on the part of the U.S. importer of record.[13] Table II contains the largest importers of diverted drugs, ranked by the entry value of the merchandise in the documents obtained from the FDA.

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12 "Dangerous Medicine: The Risk to American Consumers from Prescription Drug Diversion and Counterfeiting," Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, 99th Cong., 2nd Sess., Committee Print 99-Z (hereinafter cited as "Committee Print 99-Z").

13 H.R. 4820, which embodies the Subcommittee recommendations, if enacted into law in its present form would make the sale of prescription drugs initially sold only for export a felony. With strictly limited exceptions, it would also outlaw the reimportation of pharmaceuticals produced in the United States and shipped abroad.

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TABLE II

IMPORTERS OF DIVERTED DRUGS
(TOP TEN)

COMPANY	ENTRIES	ENTERED VALUE
Sona Distributors	30	$2,740,000
Mi-Scott International	9	$1,112,000
Westhampton	1	$560,000
Limis/Limax Wholesalers	8	$557,000
Habarx Distributing	7	$547,000
Rx Wholesale Supply	6	$462,000
Victoria Sales	5	$451,000
Quality King	5	$367,000
National Business	10	$364,000
Empire Sales	1	$350,000
Others with three or more entries:		
Trevor F. Maingot	10	247,000
MWM Chemical	3	$75,000
Rageo Properties	3	$54,000
Gulf Drug	3	$25,000

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Several patterns are worth noting. Sona Distributors, importing through its Miami, Florida office, is by far the largest reimporter of these pharmaceuticals. The staff has obtained more information about Sona's operation than is normally available because of an interview conducted at Elmcrest Trading Company, Ltd. in Hong Kong,[14] and from documents filed in a civil suit by Johnson & Johnson against Sona and Elmcrest.[15]

Of the thirty entries over this period made by Sona, all were made through the Port of Miami. The affidavits state that Sona is a Kentucky corporation with offices in Louisville, Kentucky; Miami, Florida; Columbus, Ohio; Morton Grove, Illinois; and Woodside, New York. In December 1985, Sona agreed to cease selling pharmaceuticals entered as American Goods Returned in the State of Florida after October 15, 1985 in return for not being charged with "sale and holding of drugs that are potentially adulterated and misbranded". No entries were found for other ports, although Sona has a wholesale license to sell pharmaceuticals in New York.[16] In fact, at least four shipments of reimported pharmaceuticals appear to have been entered by Sona after October 15, 1985.[17] The State of Florida issued a "stop sale" order against the Sona inventory in Miami on November 12, 1985.

Sona imported its entire $2.7 million worth of pharmaceuticals from two sources, Elmcrest Trading in Hong Kong and Satim Pharmacare in Singapore. Sona and Elmcrest are owned by the same persons and Elmcrest

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14 Committee Print 99-CC.

15 Ortho Pharmaceutical Corporation and Johnson & Johnson (Hong Kong), Ltd., v. Sona Distributors, Inc., and Elmcrest Trading, Ltd., U.S. District Court, Southern District of Florida, Case No. 86-0032 (hereinafter cited as "Johnson & Johnson Case"). This includes affidavits and depositions obtained in Hong Kong.

16 Id.

17 FDA Sample #'s 778263, 778264, 778265 and 778318.

(Footnote continued)

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sold to no other U.S. diverter.[18] No inquires were made by either the Subcommittee staff or Johnson & Johnson in its lawsuit regarding the ownership of the Singapore firm.

Elmcrest bought much of the merchandise supplied to Sona from the Chung Ching Pharmaceutical Company (also known as Chung Ching Dispensary, Ltd.) of Hong Kong, a wholesaler. According to the deposition of Mr. Ling Yee Lung, manager and pharmacist for Chung Ching (taken May 9, 1986 in connection with the Johnson & Johnson lawsuit), he was told by Mr. Andrew Wong and Mr. Inder (Satinder S. Chawla) of Elmcrest to tell the Hong Kong office of Johnson & Johnson that the purchases were intended for export to the People's Republic of China. He was also asked to keep the name of Elmcrest "top secret." Mr. Lung wrote a letter on January 3, 1986 confirming, "Our customer told us that the goods were then resold to the People's Republic of China by our customer." Both Andrew Wong and Satinderpal (Satinder) S. Chawla signed affidavits in Hong Kong on January 24, 1986 stating that neither they nor anyone else at Elmcrest told Chung Ching that the goods were intended for the People's Republic of China. These are not contradictory statements.

Records supplied to the Subcommittee through normal channels from the Orlando, Florida District Office of the FDA were incomplete. However, the staff made a cursory examination of the Sona files in Orlando. It would appear that, in most cases, the goods were supplied by Chung Ching to Elmcrest and that Chung Ching obtained them from manufacturers' representatives in Hong Kong.

According to Mr. Lung (also known as Mr. Lin and

17(continued)
The unloading port in all cases was Chicago, Illinois. The documents do not reveal whether or not the goods continued to Miami where entry was made.

18 Johnson & Johnson Case. The owners are Kulraj S. Chawla, New York; Harwinda S. Chawla, New York; Satinder S. Chawla, Florida; Davinder S. Sahni, Kentucky; and Manject S. Chawla, New York.

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as Mr. Lam, depending on the Chinese dialect used) of Chung Ching, the initial sale to Elmcrest was made on July 19, 1984. The Chawla Affidavit states that Elmcrest Trading was incorporated in Hong Kong in March 1984. It is not known if there was a predecessor firm; however, Mr. Chawla describes Elmcrest as "a trading company which primarily buys and sells electronics, pharmaceuticals and photographic equipment and supplies to Sona Distributors, Inc."[19] According to testimony and documents entered into the Subcommittee's Hearing Record on March 6, 1984, Sona had been caught by the Customs Service entering Kodak film worth $1,516,819, misdeclared as American Goods Returned to avoid duty of $66,739 from the period May 18, 1983 to July 12, 1983.[20] This was picked up in a regulatory audit by the Customs Service. Because Customs did not attempt to show fraud, they were limited to the recovery of ninety days worth of entries, despite the fact that the audit showed Sona misdeclarations dating back at least to 1982. In 1982, Sona's entries through the notorious Free Trade Zone in Miami totaled $6.6 million. It is unknown if Sona was dealing in pharmaceuticals at that time.

Even if the pharmaceutical entries did not begin until the summer of 1984, millions of dollars worth of diverted merchandise were reimported by a single U.S. firm employing only two foreign sources but involving the goods of at least twenty different pharmaceutical manufacturers.

Further, Sona had only one customer -- P.D.I. Enterprises of 7277 Hayvenhurst Avenue, Van Nuys, California.[21] P.D.I. is owned by Irwin Schaffer. According to a Subcommittee staff interview with Mr.

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19 Id.

20 "Unfair Foreign Trade Practices (Part 3)," Hearings before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, 98th Cong., 2nd Sess., Serial No. 98-164, pp. 215, 286-293, 306-07.

21 Johnson & Johnson Case.

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Marvin Sandler of Interstate Drug Exchange, Mr. Schaffer alleges very close ties to Bergen Brunswig, a large, California-based wholesaler often reputed to be a major purchaser of diverted drugs.

Far less is known about the activities of the other large reimporters identified in Table II. Mi-Scott International of Miami, Florida has the second largest declared value ($1.1 million), but most of this was attributable to products generally considered health and beauty aids. The third largest total involved a single shipment of $560,000 worth of Pfizer products. The reimporter of record was Westhampton Group, Inc., of Culver City, California.22 This shipment is discussed in a later section of this report.

The role of brokers is worth noting at this point -- not the Customs brokers who process entry documents for a small fee, but the middlemen who import for a limited clientele. Sona Distributors sold exclusively to P.D.I. Trevor F. Maingot of St. Catherine's, Ontario, Canada made ten entries through Boston, all apparently bound for either Quality King or Victoria Sales of New York, or H.L. Moore Drug Exchange of New Britain, Connecticut.23 Quality King, Victoria Sales and H.L. Moore are well-known dealers in diverted merchandise. Quality King has the distinction of being the only wholesaler known to have been involved with all three counterfeit incidents discovered in the past eighteen months.

Abdor, Inc., a New York company entering goods through San Francisco, California, had only two shipments valued at $123,457. However, this firm was one of three sources used by Interstate Drug Exchange, which reimported millions of dollars worth of pharmaceuticals annually until the spring of 1985.24

The interrelated business arrangements among diverters is also of interest. One firm operating out of New York and New Jersey but importing through San

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22 FDA Sample #'s 868278-85.
23 FDA Sample # 574072.
24 Subcommittee staff interview with Marvin Sandler.

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Juan, Puerto Rico and Boston, Massachusetts sometimes uses the name Limis Wholesalers and sometimes Limax Wholesalers. Arthur Weitzman is often listed as the importer of record, but correspondence was received by FDA Boston identifying the President of the firm as Lena Lederman.

The listed address for Limax Wholesalers is 35 Doyle Court, East Northport, New York. According to information received from a pharmaceutical manufacturer trying to trace Limax Wholesalers, no such company exists at that address; however, there is a listing for National Business Enterprises at that address. The principal of this firm is believed to be Bernie Applebaum. Neither Limax Wholesalers nor National Business Enterprises is licensed to possess prescription drugs in the State of New York.25 National Business Enterprises, sometimes doing business as Worldwide Enterprises, made ten entries through Philadelphia, Pennsylvania and Miami, Florida valued at $363,937, according to the FDA documents.

Limis/Limax obtained Upjohn and Ayerst products from the Philippines and Lederle products from Cyprus and Nigeria. National Business Enterprises received Upjohn products from the Philippines, Singapore and Jamaica. They also had a source on Guam for Barnes-Hind products. Some of the documents supplied to FDA Boston to obtain release of Upjohn goods from the Philippines to Limis/Limax appear to have been falsified.

Habarx Distributing Corporation received diverted goods of a number of manufacturers from several sources in the Caribbean, and used both Miami and Boston to attempt to enter the same goods. This will be discussed later in the report. When using Miami, the importer of record was usually listed as International Shipping Group, a Miami firm. Ben Ramos, the individual representing International

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25 This information was provided in response to a Subcommittee survey of pharmaceutical manufacturers regarding known or suspected diversion of their products.

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Shipping Group, also uses the stationery of Benel International. Habarx also imported Du Pont pharmaceuticals initially destined for Malta.

No discussion of the activities of U.S. diverters could be complete without reference to Rx Wholesale Supply of Miami, importers of both counterfeit and genuine Eli Lilly Ceclor antibiotic. Rx Wholesale was owned and operated by the Vigdor family. Niv Vigdor was the President, but his father, Zeeve Vigdor and mother, Ruth Vigdor, were also Directors. It is presumed that the firm is now defunct, since they entered into a stipulation with the State of Florida In December 1985 agreeing to re-export drugs subject to a "stop sale" order to the source of supply or to an approved distributor, and:26

> [N]ot to obtain any type of Florida license to handle, deal, store, distribute or dispense medicinal drugs or to be involved in any Florida license facility handling or brokering medicinal drugs.

This stipulation applies to the Vigdors individually, as well as Rx Wholesale Supply, Inc.

In return, the State of Florida agreed not to file charges regarding the following violations:27

> (1) the sale or offering for sale or holding of drugs that are potentially adulterated and misbranded or had otherwise rendered unfit for human or animal use;
> (2) receipt of drugs which are potentially adulterated and misbranded;
> (3) incomplete and unavailable records of medicinal drug transactions;
> (4) doing business at an unregistered address;
> (5) incomplete audit trail of medicinal

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26 State of Florida Stipulation, December 20, 1985 -- retained in the Subcommittee files.

27 Id.

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drugs on hand;

(6) obtaining medicinal drugs at three unpermitted businesses: Niroda, Natili, and Incomex.

Additionally, the stipulation charges that Rx Wholesale did not have all drugs examined at least every four months, and failed to remove drugs which had reached their expiration date.

The Subcommittee staff interviewed the Customs broker employed by Rx Wholesale to enter pharmaceuticals through the Port of Boston. He believed that at least one of the Vigdor firms, Incomex, is still actively involved in reimportations of perfumes and other beauty aids, principally through the Port of Miami.

Rx Wholesale Supply made five entries through the Port of Boston valued at $462,234, according to the FDA documents. One shipment involving $176,293 entered value of Du Pont products will be discussed later. Another entry involved six thousand pieces of Premarin Vaginal Cream imported through Galaxy International from Ayerst Laboratories (Philippines). FDA has refused to admit the merchandise at the request of Rx Wholesale, and it will presumably be reexported to Hong Kong. Another shipment involving Halog Cream and Enduron Tablets from Multipharmaceutical Company in Singapore has also been refused admission by FDA and is scheduled for reexport.

The remaining entries involved $330,000 worth of Eli Lilly's Ceclor, entered with counterfeit labeling and packaging. A small quantity of Wyeth's Sparine was included with one Ceclor entry. The best information available suggests the Ceclor traveled the following route:

The drug was probably manufactured in the Eli Lilly facility in Basingstoke, England. It was in capsules of a different shape than those manufactured in the United States and contained a dye not approved for use in this country. The Ceclor was likely part of a large shipment sold to the Malaysian military. FDA Boston was given invoices on one shipment showing the drugs were shipped from Eli Lilly (Puerto Rico) to

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J.L. Morison and Sons, Malaysia. This invoice was almost certainly a forgery.

It is likely that the counterfeits did pass through the hands of J.L. Morison, Malaysia, the former Eli Lilly agent. From there, they went to two Singapore firms, Multipharmaceutical Company and Oscar Pharmaceuticals. The Oscar shipment traveled through Galaxy International of Hong Kong. The Multipharmaceutical shipment went directly to Paris for the account of Ronidaz International, which combined it with goods from Galaxy International. Both shipments arrived in Boston in late August 1985.

The Subcommittee staff interviewed persons at Oscar and Galaxy last February.[28] The principal at Galaxy International, K. Jeswani, acknowledged part ownership of Oscar. Oscar acknowledged being offered suspicious-looking Ceclor by Multipharmaceutical. In an interview with the FDA, Zeev Vigdor said he believed that Galaxy and Oscar jointly owned the Swiss firm, Ronidaz International, and that Multipharmaceutical was the same as Oscar. Further, Mr. Vigdor believed that all four firms may be subsidiaries of Good Value Properties, Ltd. of Singapore.[29]

That interview also revealed that Quality King had paid Rx Wholesale in advance for part of the Ceclor. Victoria Sales in New York also acquired some Ceclor from Oscar Pharmaceuticals that the FDA tested and found to be of U.S. origin.[30] Apparently, Rx Wholesale was involved in that sale or a similar transaction where part of a Ceclor shipment destined for Victoria Sales was shipped to Galaxy International by Quality King.[31]

The fact that the authorized Eli Lilly representative in the area was apparently involved in

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28 Committee Print 99-CC.

29 FDA Memorandum of Interview, November 15, 1985, by Jeanne Bush and Veronika Fabritzky, Miami District Office.

30 FDA Sample # 574180.

31 FDA Memorandum, November 15, 1985.

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the diversion of genuine and counterfeit Eli Lilly products illustrates the practical impossibility of relying on a paper trail alone to deny or allow entry of reimported pharmaceuticals. Moreover, in December 1985, Lad Drug Company, an authorized Eli Lilly wholesaler in Rosemead, California, notified Eli Lilly that they had six bottles of Ceclor 500 mg. with Thailand registration stickers. Lad Drug found the Ceclor while searching for counterfeit products in October 1985. Lad Drug obtained the Ceclor from Interstate Cigar Company as part of three shipments between June and August 1985.32

Mr. Vigdor apparently received one thousand "white" bottles of Ceclor in June 1985 which he later exported.33 Eli Lilly sells Ceclor in the United States in brown bottles. The FDA procured an August 2, 1985 telex from Mr. Jeswani to Mr. Vigdor which stated that all future Ceclor will be shipped in brown bottles and requested that Mr. Vigdor try to dispose of the one thousand white bottles of Ceclor 250 mg. which had been rejected by Interstate Cigar Company.34

Mr. Vigdor also acknowledged to the FDA that four or five shipments of pharmaceuticals from overseas were financed by Rx Wholesale but actually were imported by Habarx Distributing Corporation. Some of the merchandise went to Allou Distributors. The medicines apparently included Aldomet, Cogentin, Cuprimine, Aramine, Sparine, Unipen and Urecholine.35

Quality King also apparently attempted to procure products of Bausch and Lomb, Abbott Laboratories, CIBA-GEIGY, Upsher-Smith, Winthrop-Breon and Miles Laboratories from Rx Wholesale which were never delivered.36

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32 FDA Memorandum of Interview, February 7, 1986, by Calvin Foulks, Detroit District Office.

33 FDA Memorandum, November 15, 1985.

34 Id.

35 Id.

36 Id.

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IV. FOREIGN SOURCES OF DIVERTED DRUGS

In the last eighteen months, counterfeit drugs or medications with counterfeit labeling have entered the United States from Panama and Singapore. As discussed in other recent Subcommittee and staff reports, the clear and present danger to the public health from reimported pharmaceuticals is the threat that subpotent, superpotent, impotent or even toxic substances labeled as U.S.-produced legend drugs will enter the distribution system. The foremost danger comes from so-called "generic" drugs produced in developing countries that do not provide product patent protection for pharmaceuticals. For example, knock-offs of Smith Kline's Tagamet in Thailand range from five percent, up to two hundred percent potent.37 In at least one instance, "generic" Tagamet was found in Smith Kline packaging in Hong Kong.38

The counterfeit Searle Ovulen 21 birth control pills that reached this country had counterfeit packaging, blister packs and package inserts included. The Eli Lilly antibiotic Ceclor, while probably manufactured in the Eli Lilly facility in England, was repacked in bottles, with labeling produced by the counterfeiters. Further, in at least two cases, counterfeit invoices have apparently been provided to the FDA.

The exporting country is not a guarantee against counterfeits. Table III summarizes the top ten countries of export of reimported pharmaceuticals to the United States.

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37 Committee Print 99-CC.
38 Id.

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TABLE III

FINAL PORTS OF EXPORT TO UNITED STATES
FOR REIMPORTED PHARMACEUTICALS

PORT	SHIPMENTS
Hong Kong	33
Singapore	17
Philippines	9
Grand Cayman	8
West Germany	6
Holland	6
Panama	6
Antigua	5
Surinam	5
Guam	5

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The top three ports are countries in the Far East. This region is notorious for shipping all types of counterfeit products and other commercial contraband to the United States.39 The Sona-Elmcrest trade accounts for most of the Hong Kong shipments. Singapore is the source of the shipments of pharmaceuticals to a wide variety of diverters. Upjohn appears to have a major problem with its Philippine sales.

Another region which is fertile ground for obtaining diverted goods is the Caribbean Basin. Grand Cayman Island, Antigua, Panama and Surinam all made the top ten, but diverters were also supplied from St. Lucia, Barbados, Belize, the Dominican Republic, Grand Turk, Curacao, and the U.S. Virgin Islands. While individual Caribbean shipments, except from Curacao, Panama and Surinam, do not reach $100,000, the population of many of these countries is so small that it is curious that manufacturers would supply them pharmaceuticals in divertable quantities.

One of the answers may be that at least some of the shipments may have been represented as sales to the governments of these countries. Both the June 1985 staff report and the April 1986 Subcommittee report on drug diversion contained examples of possible involvement by foreign government officials in the diversion of pharmaceuticals.40 More testimony is expected on this subject. In the documents supplied to FDA, one shipment to H.L. Moore Drug Exchange contains an invoice for Squibb products on

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39 See especially: (1) "Unfair Foreign Trade Practices: Imitation Is Not Flattery," Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, 98th Cong., 2nd Sess., Committee Print 98-V; (2) "Unfair Foreign Trade Practices: Criminal Components of America's Trade Problem," Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, 99th Cong.,
(Footnote continued)

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the stationery of the United Nations Mission of the Government of Antigua and Barbuda.[41]

In the Boston FDA files, the staff reviewed numerous requests and arguments from reimporters or their attorneys to FDA to not notify the manufacturers of the lot numbers, apparently for fear that the numbers could be traced. When the paper trail did not extend to the manufacturer, FDA Boston usually did seek to confirm the lot numbers with the manufacturer without releasing other information regarding the reimportation. In one other case involving Antigua, Pfizer told the FDA that at least part of the shipment was intended for St. Kitt's Hospital on that island.[42] It was diverted to Trevor F. Maingot.

The European ports of lading are, for the most part, deceiving. Rarely is there any evidence of goods shipped to England, France, Germany, Holland, Belgium or Switzerland for sale in those countries, and then diverted into the United States. Rather, these are staging ports for returns from all over the Eastern Hemisphere. Diverted goods from the Middle East, Africa, Eastern Europe and even the Far East are returned to the United States through the Port of Rotterdam, the De Gaulle Airport in Paris, or other Western European sea ports and airports.

One individual actively diverting drugs through European ports is Sunil Varma.[43] He apparently services various U.S. dealers in diverted pharmaceuticals with large shipments. Varma is based in London, operating through a variety of corporate names. Using Rothwell Enterprizes and Burma Agents Company, he diverted $152,518 (entry value) worth of CooperVision products to H.L. Moore Drug Exchange in November 1985. In this scheme, he ordered the

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39(continued)
1st Sess., Committee Print 99-H; and (3) Committee Print 99-CC.

40 Committee Prints 99-R and 99-Z.

41 FDA Sample # 788491.

42 FDA Sample # 598575.

43 See FDA Sample #'s 574510, 574866, and 860278-85.

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products from CooperVision (Puerto Rico), forwarded through CooperVision, Ltd., Southhampton, England, for the account of Burma Agents. The goods were flown via Dames Air from England to the Forwarding and Handling Company of Antwerp, Belgium. From there, the goods were shipped to Boston, after stopping at JFK Airport in New York, for H.L. Moore Drug Exchange in New Britain, Connecticut, invoiced from Rothwell Enterprizes.

In February 1986, Varma diverted $161,353 (entry value) of Du Pont pharmaceuticals to Habarx Distributing Corporation. These goods were forwarded from New York to K.G. Mohnani in Valletta, Malta. From Malta, the medicines traveled back to Varma in London and were shipped to Miami for the account of International Shipping Group. When refused entry in Miami (see later discussion), the goods were shipped by LEP Transport to Toronto, Canada. They reentered the United States through Boston for Habarx Distributing Corporation in Babylon, New York.

Varma, employing the corporate name CTM, A.G., was involved in the diversion of $560,035 (entry value) of Pfizer products in January 1986. The paper trail was not complete in this case, and the goods were detained in Champlain, New York as of March 31, 1986. Pfizer apparently exported the drugs to Montreal for shipment to a destination not revealed in the FDA documents. The goods found their way to Rotterdam, Holland, and were returned to Montreal, Canada on a Soviet freighter. Varma apparently took possession as Chronometer Time and Medical, and apparently sold them to the Westhampton Group, Inc. of Culver City, California (Leslie Steinmetz, President). The merchandise was apparently trucked from Montreal to Champlain, New York.

The role of Eastern European governments in diversion is curious. Pharmaceutical manufacturers have difficulty selling in these markets except through state trading companies. At the Subcommittee's September 19, 1985 hearing, testimony was received regarding D.A.L. International Trading Company, a Polish state trading company.44 That scheme employed LEP Transport, the forwarder used by Varma in the Habarx deal.

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Rx Wholesale Supply entered $76,293 (declared value) worth of Du Pont pharmaceuticals through Boston on September 3, 1985 from Ronidaz International Corporation of Geneva, Switzerland. The goods were shipped from Paris by Marc Air International.[45] Du Pont had sold the pharmaceuticals to Transimpex, the Bulgarian foreign trade organization. The attorneys for Rx Wholesale told FDA Boston that the goods had been trucked from Sofia, Bulgaria to Paris, France but no records were provided FDA. At some point in the process, Amiran Ben-Yemini of the Israel Container Line in Hamburg, West Germany had title to or possession of the drugs.

The pharmaceuticals involved were Coumadin, and Symmetrel. In an interview with FDA personnel in Miami, Zeev Vigdor of Rx Wholesale was asked about a shipment of Coumadin and Symmetrel he sold to Quality King.[46] He said that the shipment was originally consigned to the Bulgarian Ministry, but actually was shipped to Rotterdam, Holland, and then back to France for export to the United States. When the Miami FDA investigator asked Mr. Vigdor for the documents, he supplied only a packing list, Du Pont invoice and certificate of origin. Unlike the documents supplied to FDA Boston in connection with release of the goods, these documents did not show the consignee. The FDA memorandum states:[47]

> I asked Mr. Vigdor why these names were not on these documents and he stated that the officials in Bulgaria, who were previously paid off, did not wish to disclose their identity. (Emphasis added.)

In a shipment where similar documents were produced, the Government of Czechoslovakia may have been involved.[48] Victoria Sales imported $41,000

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44 Hearings, 99-61, pp. 270-75.
45 FDA Sample # 574161.
46 FDA Memorandum, November 15, 1985.
47 Id.

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(declared value) worth of Barnes-Hind products through Boston on September 8, 1985. Barnes-Hind had sold them to Bromex Trading, Ltd., c/o Pragent, Prague, Czechoslovakia. They were exported to the United States by Oridan Trading, Ltd. and shipped from Brussels. Victoria Sales claims the goods were shipped from Prague to Brussels, but provided no shipping documents.

In another complex case, Masel Supply Company of Brooklyn, New York imported $344,105 worth of Marion Laboratories products through New York on January 15, 1986.49 As of March 31, 1986, they were being detained in New York because the documentation was incomplete. The goods were shipped from Rotterdam by AVCB, an Amsterdam firm. However, the invoice was from Fabric, Ltd. of London to Thrifty Cosmetics, Inc. of Brooklyn. Further, all products had Department of Defense numbers on them. An AVCB letter certifies, "Since their arrival from Budapest, been stored in our transit warehouse under good conditions...."

The documents contain several other diversion routes of particular interest. One is the Cyprus-Lebanon connection. In August and September 1985, shipments came to Boston for Limax Wholesalers from InterTrading S.A.R.L. of Limassol, Cyprus.50 Both shipments involved Lederle products totaling $370,000 in declared value. The shipments had been destined for Mercury S.A.L. in Beirut, Lebanon. It is likely that they only got to Larnaca Airport in Cyprus before being re-routed back to the United States.

Winthrop-Breon and Norwich Eaton both had products diverted through Dubai, United Arab Emirates to Victoria Sales in New York.51 The entries were made in November 1985 (Norwich Eaton) and January 1986 (Winthrop-Breon) for entered values of $216,240 and $107,000, respectively. In both cases, the listed

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48 FDA Sample # 574149.

49 FDA Sample #'s 660885-7.

50 FDA Sample #'s 574064-5 and 574510.

51 FDA Sample #'s 574509 and 574735. See also FDA Sample #'s 771222-5.

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exporter of record was Alpha Al Khalij. His November 1985 address was in West Germany, and in January 1986, he claimed Dubai as his home. Both entries involved Merchants Corporation of America in Zurich, Switzerland.

In another Middle East deal, Limax Wholesalers acquired $27,600 worth of Lederle products from Innovation Investors, Ltd., of Lagos, Nigeria.[52] Lederle sold the goods to Neopharm, Ltd. of Tel Aviv, Israel. Neopharm shipped them to Marc Air in Paris, to be sent to Lagos. The Innovation shipment to Limax Wholesalers also traveled through Marc Air at De Gaulle Airport.

Norman Goldstein acquired title to $51,902 (entry value) of Penwalt products from Rotterdam through Philadelphia, Pennsylvania, in July 1985.[53] As of March 31, 1986, the goods were still detained and the documents are incomplete. However, the Penwalt invoice shows the goods sold to Mr. Claude Socroun, Chairman of AFT International Corporation, Little Neck, New York, but shipped to the Societe Vimaud in Dakar, Senegal.

Several entries suggest that some goods may have actually circumnavigated the globe. Victoria Sales bought Bufferin, which they claimed was shipped from Bristol-Myers (USA) to its Hong Kong agent, then to Bremen, West Germany before reaching the Port of Boston on September 12, 1985.[54] Parke-Davis suppositories entered at a value of $349,544 (detained in New York as of March 31, 1986), were shipped by Fabric, Ltd. of London, England, through Brussels, Belgium to JFK Airport, New York for Empire Sales of Brooklyn, New York. Documents indicate the goods came from Warner-Lambert (Hong Kong).[55] Bellarno International of New York entered $47,382 worth of Norwich Eaton products from Singapore via Greece.[56]

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52 FDA Sample # 576433.
53 FDA Sample # 525580.
54 FDA Sample # 574142.
55 FDA Sample # 704310.
56 FDA Sample #'s 660848-51.

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These goods also were detained by FDA as of March 31, 1986.

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V. DO PHARMACEUTICAL MANUFACTURERS REALLY EVER CHANGE THEIR SPOTS?

There can be no doubt that stockholders and others who depend on the economic well-being of the pharmaceutical manufacturing concerns are victims of drug diversion. Pharmaceuticals reimported by diverters displace full price sales in the wholesale market. Moreover, prices to ultimate consumers are generally not lowered as a result of diversion. Rather, the profits go to the various middlemen, here and abroad, while consumers bear the risk.

Within the pharmaceutical manufacturing company there are also winners and losers. Winners are the sales agents and sales divisions which get credit for the sale. Losers are the company coffers and those sales agents and sales divisions whose business is reduced due to the presence of diverted product in their territory.

Finally, patterns of corporate concern -- or the relative lack thereof -- are emerging from the Subcommittee's investigation. Tables IV and V detail the top ten manufacturers of pharmaceuticals whose product was found in the review of the FDA documents. Table IV ranks manufacturers by entries and Table V by entered value of the diverted products.

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TABLE IV

MANUFACTURERS' GOODS DIVERTED
(BY ENTRIES)
(TOP TEN)

COMPANY	ENTRIES
Upjohn	30
Bristol-Myers	15
Marion Laboratories	10
Squibb	10
American Home Products	8
Procter and Gamble	8
Schering-Plough	8
Abbott Laboratories	6
Eli Lilly	6
Pfizer	6

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TABLE V

MANUFACTURERS GOODS DIVERTED
(BY ENTERED VALUE)
(TOP TEN)

COMPANY	ENTERED	VALUE
Marion Laboratories	$1,300,000	($383,000)
Upjohn	$934,000	($719,000)
Pfizer	$784,000	($638,000)
Parke-Davis	$780,000	($367,000)
Squibb	$776,000	($270,000)
Bristol-Myers	$741,000	($285,0000
Carter-Wallace	$686,000	($280,000)
Johnson & Johnson	$633,000	($81,000)
Eli Lilly	$515,000	($210,000)
American Home Products	$504,000	($25,000)

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Table V requires further explanation. Many of the entries contain the products of two or more manufacturers. As noted earlier, it was impossible to meaningfully separate the entered value of each product in these commingled shipments. The dollar figure used in this ranking is the aggregate entered value of all shipments including one or more of the products of that manufacturer. The dollar figure in parenthesis is the entered value of shipments containing only the goods of that manufacturer.

On September 19, 1985, Stanley Kowitt, a pharmacist and wholesaler of diverted drugs, testified before the Subcommittee. He produced for the record or review by the staff voluminous documents showing sales by manufacturers to hospitals in quantities well beyond their conceivable use. Those documents, acquired in connection with his criminal trial, covered the period 1974-79. In his testimony, Mr. Kowitt stated:57

> In my twelve years of buying and selling diverted merchandise, I found that certain companies' products always seemed to be available in large quantities from many different sources and other companies' products seemed hardly ever to be available. Abbott, Allergan, Bristol, Cooper, Lederle, Mead Johnson, Merrill-Dow, Syntex, Wallace and Warren Teed -- now Adria -- goods were plentiful, while Lilly, Burroughs-Wellcome, Merck Sharp & Dohme, Smith Kline Beckman and Upjohn goods were very scarce. All other companies' products fell somewhere in between with merchandise available intermittently.

Table VI notes the number of entries and entry value of shipments containing merchandise produced by the firms listed in the Kowitt testimony for the six months covered by the FDA documents.

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57 Hearings, 99-61, p. 77.

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TABLE VI

MANUFACTURERS OF DIVERTED PRODUCTS
NAMED IN KOWITT TESTIMONY

MOST COMMON	ENTRIES	ENTERED VALUE
Abbott	6	$299,541
Allergan	0	$0
Bristol-Myers*	15	$741,366
Cooper	1	$152,518
Lederle	4	$421,131
Merrill-Dow	0	$0
Syntex	0	$0
Carter-Wallace	2	$686,262
Adria	0	$0

Least Common	Entries	Entered Value
Eli Lilly	6	$514,809
Burroughs-Wellcome	0	$0
Merck Sharp & Dohme	2	$436,969
Smith Kline Beckman	0	$0
Upjohn	30	$933,618

*Includes products of Bristol-Myers and Mead Johnson.

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The biggest surprise is that Upjohn, the company with the largest amount of diverted product entered as American Goods Returned, was named by Mr. Kowitt as rarely having goods in the diversion market. That firm has obviously sprung some leaks, the largest coming from the Philippines. Nine entries of Upjohn products ranging from $15,600 to $67,050 were traceable to Upjohn Manila. Six other entries from Hong Kong and Singapore may also have a Philippine connection.

The Caribbean Basin also is a source of Upjohn products. Two entries from Antigua, three from Grand Cayman Island, and one each from Belize, St. Croix and Jamaica found their way to the United States. Five shipments involved a bulk pharmaceutical from West Germany. The documents even include a sample shipment from Yugoslavia.

A shipment of $30,720 (entered value) of Merck Sharp & Dohme drugs came to National Business Enterprises from the Philippines. The remaining entry involving Merck was for $406,249 (entered value) from Elmcrest Trading to Sona Distributors and included the merchandise of five manufacturers.

The bulk of the Eli Lilly merchandise imported was either U.S.-manufactured Ceclor or Ceclor with counterfeit labeling. These goods came either from Singapore directly, or through Paris, France. Sona got some of the genuine Ceclor from Elmcrest in Hong Kong. The remaining Eli Lilly drug was shipped to Veterinary Services in Modesto, California from Toronto, Canada.

Of the manufacturers of diverted product most often found in the market according to Mr. Kowitt, four had no product entered as American Goods Returned, according to the FDA documents. Allergan, Adria, Merrill-Dow, and Syntex were the firms. Merrill-Dow now employs a one-price policy, so its exclusion was predictable.

Bristol-Myers is an interesting case. After Mr. Kowitt testified, Mr. William Greif, Vice President of Bristol-Myers, wrote Chairman Dingell a letter of clarification.[58] After noting that, "... the problems identified by Mr. Kowitt occurred almost ten years ago, and were corrected at that time," Mr. Greif went

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on to state:

> Since that time, the Company has taken steps to alert itself to unusually large purchases relative to an individual customer's needs, including the training of company personnel to identify attempts to divert any significant quantity of our products, and to take appropriate action.

Perhaps Mr. Greif was merely referring to diversion of Bristol-Myers and Mead Johnson products from health care institutions in this country. In terms of the FDA documents, Bristol-Myers products are second in number of entries and sixth in terms of entered value. Bristol-Myers products have reentered from Hong Kong (Sona Distributors [two shipments], Quality King, and H.B.F. Products), West Germany (Victoria Sales), Guam (MC International), and even Bangladesh (Syage). Mead Johnson products were entered from Singapore or Hong Kong to Sona on six different occasions. MC International got Mead Johnson products from Guam and BHS procured them from Hong Kong.

Carter-Wallace and Abbott Laboratories were the other manufacturers to make Tables IV/V and VI. Sona got $280,013 (entered value) of Carter-Wallace product from Singapore, and their goods were included with four other manufacturers in a $406,249 shipment from Elmcrest to Sona. Abbott products were included in five shipments from Elmcrest to Sona and one to Rx Wholesale from Singapore through Paris.

Lederle Laboratories had about $670,000 worth of product diverted in 1985 which does not appear in the abstracts because it never actually left the United States. Lederle's Honduran office was involved in a scheme that diverted Pipracil intended for sale in that country to Military Exchange Buyers Overseas, Inc. in Miami Beach, Florida. The medicine was produced in Puerto Rico and diverted while en route at

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58 Hearings, 99-61, pp. 290-91.

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the Miami airport. Before the Pipracil was sold to other diverting companies, the original Spanish packaging and labeling was replaced with counterfeit English language versions. Bernard Klepach is the President of Military Exchange. Julio Klepach, Bernard's father, is alleged by Lederle to have aided the diversion scheme. On May 19, 1986, Lederle obtained a Final Judgment and Injunction by Default of $1,004,430 actual damages and $1 million punative damages against Military Exchange and the two former Honduran employees. Quality King, Habarx Distributing Corporation and Rx Wholesale Supply all received and disseminated the counterfeit labeled Pipracil.

The Lederle products reimported into the United States include those shipments from Cyprus and Nigeria discussed earlier. Additionally, $24,218 worth of Lederle product was entered in San Juan, Puerto Rico from the Dominican Republic by Arguelles, a diverter identified in previous testimony.

Other pharmaceutical manufacturers whose product has been reimported with some regularity include Marion Laboratories, Squibb, Parke-Davis and Schering-Plough. American Home Products and Procter and Gamble both appear on Tables IV and V, but their entries largely involve over-the-counter products and/or health and beauty aids.

Marion products were involved in six Elmcrest to Sona shipments, two shipments from Grand Cayman, an Abdor shipment from Hong Kong and the $344,105 entry to Masel Supply from Holland.

Squibb products reentered from more diverse sources. Sona received two shipments from Hong Kong, and Rx Wholesale obtained material from Paris. The rest of the Squibb entries were from the Caribbean. Over $200,000 in entered value came from Surinam, two shipments arrived from St. Lucia, and one each from Grand Cayman, Antigua and Jamaica.

Parke-Davis products were involved in two Elmcrest to Sona shipments, the large diversion to Empire Sales noted earlier, and a shipment from Belize to the Third World Fund, possibly a charity.

Schering-Plough also has problems in the Caribbean. Two shipments were entered via the Elmcrest to Sona route. However, three others were

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entered from Barbados, two from Panama and one from Curacao.

A special mention should go to Barnes-Hind, which managed to have almost $200,000 (entered value) worth of eye-care pharmaceuticals diverted from Guam, an island of less than 90,000 people. Antigua, including Barbuda and Redona, has a population of only 60,000. St. Lucia's population is 101,000 and Grand Cayman's population is only 10,000.

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VI. THE FDA RESPONSE TO PHARMACEUTICAL DRUG DIVERSION

As noted earlier, FDA was slow to react to the drug diversion problem even after it was discovered that the counterfeit Ovulen 21 was entered as American Goods Returned. This is not surprising. Like most agencies charged with enforcement responsibilities, FDA has been caught between growing problems and shrinking budgets for most of the decade.

According to a recent report by the Inspector General of the Department of Health and Human Services (HHS):59

> The limited review of FDA procedures that was possible in the time allotted for this investigation indicated that these procedures are largely geared to investigations involving regulation of legitimate entities. As such, they do not comfortably apply to large-scale organized criminal activity as is frequently found in the relatively new drug diversion and counterfeiting schemes.... Because there is little hope that the problem of drug diversion will not continue, it may be advisable for FDA and the Department (HHS) to re-examine its handling of diversion and counterfeiting allegations.

That report, not yet publicly released, details the cumbersome procedures FDA follows in its investigations. FDA has broad authority regarding reimported pharmaceuticals. According to the General Counsel of HHS:60

> [D]rugs that are imported into the United States and that <u>appear</u> to be adulterated or

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59 Letter from Richard P. Kusserow, Inspector General, HHS to Chairman Dingell, July 2, 1986.

60 Letter from Ronald E. Robertson, General Counsel, HHS to Chairman Dingell, June 13, 1986 -- retained in the Subcommittee files.

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misbranded may be refused admission by the FDA, working in conjunction with the U.S. Customs Service. 21 U.S.C. Sec. 381(a). (Emphasis added.)

Commissioner Young, having refused to sample each entry of reimported pharmaceuticals, did implement the experimental control program described in Chapter 1.

On September 6, 1985, an import alert was issued to all districts by FDA Headquarters. The "Guidance" section of that alert reads as follows:61

> Automatically detain all entries of bulk and dosage form drugs declared as 'American Goods Returned' charging: 'The article is violative within the meaning of 801(a)(3) in that it appears the item is a new drug without an effective new drug application as required by Section 505(a); and is adulterated within the meaning of Section 501; and is misbranded within the meaning of Section 502.'
>
> No entry shall be released unless and until the owner or consignee (importer) establishes the following:
>
> 1. A complete chain of custody (through adequate documentation such as shipping records, Manufacturers Certificate of Origin, etc.) tracing the goods back to the original U.S. manufacturer which assures the drugs were manufactured in the United States. In the absence of a Manufacturers Certificate of Origin it should be established through validation from the U.S. manufacturer that the lot numbers on the drugs are valid production runs. This should be done with care not to divulge valuable commercial information and trade secrets such as shipper's name, etc., which are protected under the FD&C Act, FOI,

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61 FDA Import Alert #66-14, September 6, 1985, by Richard R. Klug, Director, Import Operations -- retained in the Subcommittee files.

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and the agency's regulations.

2. The expiration date has not been exceeded.

3. There is satisfactory reason for the return of the goods and the reason is not indicative of a violation of the Federal Food, Drug, and Cosmetic Act.

4. There is no adulteration and/or misbranding of the goods. Evidence showing no adulteration and/or misbranding may need to be established through certification by private laboratory examination (i.e., potency, sterility, meets official compendium standards, etc.)

In addition to issuing a Notice of Refusal of Admission, when the importer fails to respond to the Notice of Detention and Hearing or cannot establish a chain of custody back to a U.S. manufacturer, conduct an investigation of the importer to determine all of the facts and circumstances surrounding the importation. If it appears that further action by Customs (i.e., false declaration proceedings) or FDA (i.e., seizure, prosecution, injunction) is necessary, make appropriate recommendations.

In order to prevent the possible diversion of refused shipments arrange followup with local U.S. Customs officials to assure that the actual goods are redelivered, exported, or destroyed.

In connection with #4 above, request private laboratory examination of those pharmaceuticals that are subject to adulteration, potency change (deterioration, etc.) due to age, improper storage conditions, etc. Also conduct audit sampling of a representative number of shipments.

A revised import alert was issued on October 1, 1985, specifying:62

Manufacturers Certificate of Origins received with recent entries were not issued by the U.S. manufacturers but by the foreign shippers or

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other foreign firms. These are not acceptable. Therefore, validation with the alleged U.S. manufacturer must be made.

Further instructions were issued on October 30, 1985:63

> While there are legitimate reasons for returning American goods, in many instances, the items are returned because they are adulterated and/or misbranded. Violative goods, if not examined, may reenter the United States for distribution without proper reconditioning or relabeling.
>
> All American Goods Returned must be considered suspect (please see Import Alert #66-14 for coverage of pharmaceutical products.) We suggest that all entries of such imports be given serious consideration before they are released. Determine the reason for the return of the goods. The goods should be wharf examined in all cases and sampled for laboratory examination when there does not appear to be a legitimate reason for return of the goods, or when the physical appearance of the goods indicates possible violations (stained containers, etc.).

The first import alert to the field regarding fraudulent documentation was issued "on or around 1/31/86" and re-transmitted February 21, 1986:64

> We have received reports that review of

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62 FDA Import #66-14-Revised, October 1, 1985 -- retained in the Subcommittee files.

63 FDA Memorandum, "Coverage of American Goods Returned," October 30, 1985 -- retained in the Subcommittee files.

64 FDA Memorandum, "Coverage of American Goods Returned," February 21, 1986 -- retained in the Subcommittee files.

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documents for some entries of 'American Goods Returned' revealed the products were offered for entry in less time than it would take for the products to arrive at the initial foreign consignee. These instances represent clearly fraudulent documents for 'American Goods Returned' and emphasizes the need to give serious consideration of all such entries before they are released.

We suggest thorough review of documentation for all entries of 'American Goods Returned' to ensure the documents are authentic and the entries represent products that have actually left the U.S. and are being returned. In all instances, districts need to satisfy themselves these entries are legitimate returning American goods.

All entries designated 'American Goods Returned' should be wharf examined and sampled for laboratory examination when there does not appear to be legitimate reason for return or when the physical appearance of the goods indicates possible violations (stained containers, etc.).

Finally, a full import alert was issued on May 1, 1986 incorporating procedures for dealing with these stated concerns and the possibility that diverters might seek to declare human drugs as veterinary to evade the Import Alert requirements.

FDA field enforcement certainly did not rigidly adhere to the guidance in the import alerts. They also faced differential levels of problems. Table VII lists the entry value of diverted drugs by FDA district.

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TABLE VII

AMERICAN PHARMACEUTICAL GOODS RETURNED
BY FDA DISTRICT

FDA DISTRICT	VALUE OF GOODS
Orlando, FL	$5.1 million
Boston, MA	$2.4 million
New York, NY	$1.6 million
Buffalo, NY, Dallas, TX, Los Angeles, CA, Philadelphia, PA, San Francisco, CA, & San Juan, Puerto Rico	$1.5 million

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The Subcommittee staff examined the full documentation associated with FDA decisions to detain, release, refuse entry or seize reimported pharmaceuticals only in the case of the Boston district.

In very few cases were "reasons," much less "satisfactory reasons," for reimport given FDA. The objections of the importers to FDA validating lot numbers with the manufacturers might have been reason to suspect that mail fraud or wire fraud may have occurred. False documents were apparently twice supplied to FDA Boston (the products are still under detention) which may be a violation of the Food, Drug and Cosmetic Act. Finally, the dates on most of the invoices suggests that the goods were not surplus which could not be sold abroad, but the product of schemes to obtain pharmaceuticals at prices below those obtainable in the United States.

The documents contained no evidence that private laboratory analysis was required by the FDA prior to the release of any shipment. Apparently, the resources to certify the private laboratories were not available. At least in Boston, and probably nationwide, no attempt was made to "conduct sampling of a representative number of shipments." FDA did physically analyze some samples, but only when there was obvious cause for concern.

Not all files show evidence of a Manufacturer's Certification of Origin or validation of the lot numbers, even in Boston. That office, having found the counterfeit-labeled Ceclor, was primarily concerned with stopping other counterfeits. Product was routinely released to the importer's premises. Particularly early in the program, physical inspection of the goods was waived, and in a few instances, the importers were permitted to supply the lot numbers by letter or telephone.

There is no evidence of concern by FDA field offices in any documents received by the Subcommittee about "potency change (deterioration, etc.) ... due to improper storage conditions, etc." Many shipments were made by ocean freight from locations in the Middle East, Far East and the Caribbean. These were rarely tested. They included pharmaceutical

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suppositories and injectables which are presumably very sensitive to heat. Many pharmaceuticals contain FDA mandated labeling which cautions against storage in temperatures exceeding 86 degrees Fahrenheit.

In one case, 200,000 Penicillin V Potassium USP was reimported after nine months in Bangladesh and no physical sample was taken (the goods were still detained as of March 31, 1986 because the documentation was incomplete).65 Upjohn pharmaceuticals diverted from the Philippines were often sent by ocean freight both ways. The Lederle Minocin capsules entered from Nigeria had been in the Middle East and Africa for almost six months before their return.66 They were released without laboratory analysis. Many other examples could be cited.

The minimum requirement for release was a complete paper trail back to the original manufacturer. The documents supplied the Subcommittee were not sufficiently complete to evaluate FDA field office compliance with the Headquarter's directive. Even in Boston, where a good faith effort was made to establish that the drugs were of U.S. origin, pharmaceuticals were occasionally released without complete documentation.

In Philadelphia, Pennsylvania, the FDA field office apparently disregarded the import alert altogether for three entries in January 1986. They did not sample (detain) the goods. The FDA computer list explained that, "all documentation was on hand at time of entry." In fact, the documentation supplied the Subcommittee was incomplete and some of it was apparently supplied to FDA after entry was made. There is no evidence to suggest that lot numbers were verified with the manufacturer or that any physical inspection of the goods took place.

The policies of the Orlando, Florida District Office require special notice. It should be recalled that the State of Florida had stipulations from at least two wholesalers, Sona Distributors and Rx

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65 FDA Sample # 722713.
66 FDA Sample # 574633.

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Wholesale Supply, to cease dealing in pharmaceuticals within the State. Under the Florida statute, goods returning from overseas which had not been stored in FDA approved facilities while abroad were deemed to be subject to adulteration. Sale of such commodities could be a felony under state law. Instead of cooperating with the Florida law enforcement efforts, the Orlando office of FDA has refused to release import information to the State.

As the Inspector General of HHS described the controversy:67

> The Committee also stated concerns that the FDA is not sufficiently cooperative with the State of Florida in conducting investigations. Of particular concern to the Committee staff were so-called 'American Goods Returned.' Briefly, this issue involves conflicting Federal and State policies with respect to drugs that are manufactured in the United States, shipped overseas, and then returned to U.S. markets. Under section 801 of the Food, Drug and Cosmetic Act and implementing instructions, ... the FDA will accept pharmaceuticals that re-enter the country. However, such drugs are automatically detained (with certain limited exceptions) pending a showing by the importer: (1) of a complete chain of custody of the drugs from the time of exportation to the time of return; (2) that the goods were manufactured in the United States; (3) that the expiration date has not been exceeded; (4) that there is a satisfactory reason for the return of the goods; and (5) that there is no adulteration or misbranding of the goods. If the importer can sufficiently demonstrate the above, FDA will release the drugs. However, if any or all of the above factors cannot be proved, the FDA will investigate the importations. The State of

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67 Letter from Kusserow to Dingell, July 2, 1986.

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> Florida policy, however, is apparently to prohibit the re-entry of exported drugs altogether. This discrepancy has apparently contributed to a problem in the release of information on 'American Goods Returned' by FDA to State officials. The FDA recently refused to grant a State request that the FDA routinely provide to the State import documents on 'violating' firms. When this request was denied on the grounds that the FDA was not authorized to release such information, Florida then requested that a State official be commissioned by the FDA. This request was also denied.

Further, it is not clear that Florida State officials have had to be commissioned. According to the General Counsel of HHS:68

> Investigatory records compiled for law enforcement purposes, however, may be disclosed to state and local government officials who perform counterpart functions, whether or not they are commissioned. 21 C.F.R. 20.88 (c)(2).

It should be recalled that the import alert dictated that field offices "conduct an investigation of the importer to determine all the facts and circumstances surrounding the importation," in addition to issuing a Notice of Refusal of Admission whenever the chain of custody back to the original manufacturer could not be established. This investigation was to determine if customs laws or the Food, Drug and Cosmetic Act had been violated.

Clearly, when FDA Orlando determined to refuse admission, it had the legal authority to notify Florida State authorities. On February 5, 1986, FDA Orlando refused admission to six entries belonging to Habarx Distributing Corporation, at the importer's request. Notes in the files of FDA Boston indicate

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68 Id.

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that the goods, if released, may have been seized by the State of Florida.[69] Those shipments had entry values of approximately $600,000. The goods were exported to Canada and then reentered through Boston. Two weeks before the goods arrived, Sunil Varma, the London exporter of one of the shipments, wrote FDA Boston that FDA Orlando was going to refuse admission at the importer's request so they could be reentered through Boston.

It is likely that if the State of Florida had issued a "stop sale" notice on the goods, they would have permitted re-export, but not for reimport back to the United States.

Nor did FDA Orlando refer the information contained in the files to the United States Department of Justice or the Federal Bureau of Investigation. The interest of these agencies in possible mail fraud and wire fraud violations involving diverted pharmaceuticals was well-known to FDA.

The Varma shipment, in particular, might have been of interest to the Justice Department. The Du Pont invoices were to K.G. Mohnani in Malta. However, as part of the chain of custody papers, FDA received a letter on Mohnani's stationery. The company is "Kishu's Modern Bride" and it advises, "Specialist of Wedding Accessories, Textiles for Occasions, Gifts and Perfume." It would appear doubtful that Du Pont would have knowingly sold $160,000 worth of pharmaceuticals to such a firm.

FDA Orlando was not alone. If any referrals were made to Federal investigators or prosecutors by FDA, the records do not reflect it.

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69 FDA Sample #'s 574995, 574866 and other FDA Sample #'s referenced therein.

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FDA SAMPLE #: None
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: 86-243016-4
REIMPORTER: National Business Enterprises
One Bala Cynwyd Plaza, Suite 432
Bala Cynwyd, Pennsylvania 19004
REIMPORTATION DATE: 1/19/86
VALUE: $25,817
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: Philadelphia, Pennsylvania
EXPORT PORT: Kingston, Jamaica
STATUS: Released - never detained
MEDICATION: 800 bottles Cleocin Caps 100's
U.S. MFGR., DATE OF EXPORT: Upjohn,
11/6/85
EXPORTER TO U.S.: Medimpex West Indies, Ltd.
28 Shannon Drive, Kingston, Jamaica
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Jamaica Commodity Trading Company
8 Ocean Boulevard, P.O. Box 47, Kingston, Jamaica,
date not available;
(2) T. Geddes Grant (Distributors) Ltd.
109 Marcus Garvey Drive, P.O. Box 417, Kingston,
Jamaica, 12/10/85.
NOTES: (1) FDA computer says no sample
taken (no detention) because "All documentation was on
hand at time of entry" but not in files and some
obviously supplied to FDA later.
(2) Returned to U.S. by ocean freight.
(3) "May proceed without FDA examination," signed by
Elaine C. Messa, 2/7/86.
(4) Initial invoice Upjohn (Inter American) to Jamaica
Commodity Trading is for 1000 bottles.
(5) No document Geddes Grant to Medimpex. Invoice to
Geddes Grant does not list seller and is basically
illegible.

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FDA SAMPLE #: None
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: 86-242926-9
REIMPORTER: Worldwide Enterprises
(National Business Enterprises)
One Bala Cynwyd Plaza, Suite 432
Bala Cynwyd, Pennsylvania 19004
REIMPORTATION DATE: 1/16/86
VALUE: $26,203
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: Philadelphia, Pennsylvania
EXPORT PORT: Agana, Guam
STATUS: Released - never detained
MEDICATION: 5000 Fluress 5 ml
5000 Eppy 1% 7.5 ml
1432 Eppy 0.5% 7.5 mll
1440 Soft Mate ps Daily Cleaner
U.S. MFGR., DATE OF EXPORT: Barnes-Hind,
date not available
EXPORTER TO U.S.: Antonio L. Almendras
Agana Shopping Center, Agana, Guam
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Azalea International Trading Corporation, DITC
Building, Ground Floor, Tamuning, Guam 96910,
10/30/85;
(2) Antonio L. Almendras, 12/27/85
NOTES: (1) See FDA Sample # 525861,
apparently same Barnes-Hind export shipment.
(2) See other Philadelphia entries with no FDA Sample
#.
(3) "May proceed without examination," signed by
Elaine C. Messa, 2/7/86

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FDA SAMPLE #: None
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: 86-243015-1
REIMPORTER: National Business Enterprises
One Bala Cynwyd Plaza, Suite 432
Bala Cynwyd, Pennsylvania 19004
REIMPORTATION DATE: 1/28/86
VALUE: $30,200
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: Philadelphia, Pennsylvania
EXPORT PORT: Manila, Philippines
STATUS: Released - never detained
MEDICATION: 2000 bottles Tolinase 250 mg Tabs 100's
U.S. MFGR., DATE OF EXPORT: Upjohn,
9/16/85
EXPORTER TO U.S.: Medic's International
Suite 7-A, Vernida Condominium, Adelantado Street,
Makati, Metro Manila, Philippines, 1/23/86
OTHER FOREIGN HANDLERS, RECEIPT DATES: Upjohn
(Manila), 1/23/86
NOTES: (1) See FDA Sample # 525861.
(2) See other Philadelphia entries with no FDA Sample
#.
(3) "May proceed without FDA examination," signed by
Elaine C. Messa, 2/7/86.
(4) Shipped by ocean freight to Manila.

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FDA SAMPLE #: 180696
FDA DISTRICT: San Juan, Puerto Rico
CUSTOMS ENTRY #: Not listed
REIMPORTER: Limis Wholesalers
San Juan, Puerto Rico
REIMPORTATION DATE: 9/24/85
VALUE: $15,600
UNLOADING PORT: San Juan, Puerto Rico
ENTRY PORT: San Juan, Puerto Rico
EXPORT PORT: Manila, Philippines
STATUS: Detained - document request only
MEDICATION: 1000 bottles Medrol Tabs 4 mg 100's
U.S. MFGR., DATE OF EXPORT: Upjohn, 3/5/85
EXPORTER TO U.S.: Three C's Industry
112 Levitown Avenue, Metro Manila, Philippines,
9/16/85
OTHER FOREIGN HANDLERS, RECEIPT DATES: Upjohn
(Manila), 3/5/85
NOTES: (1) Invoice to Limis Wholesalers,
Morganville, New Jersey (see other Limis entries) -
only San Juan address is for freight forwarder.
(2) Documents say sample bottles collected.
(3) Upjohn shipment to Upjohn (Philippines) was for
5760 bottles.
(4) Invoice for 1696, 504 and 144 bottles of other
(illegible) medications (Three C's Industry to Limis)
included in documents.

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FDA SAMPLE #: 436025
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-259885
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/19/85
VALUE: $97,775
UNLOADING PORT: New York or Chicago
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 200 bottles Aquasol A Caps 25000 IU
400 bottles Enduron Tabs 5 mg 1000's
1400 bottles Iberet-Folic Tabs 5 mg 60's
1911 bottles Pavabid Caps 150 mg 100's
1824 tubes Retin-A Gel 0.025% 15 gm
1344 tubes Retin-A Cream 0.05% 20 gm
1824 tubes Retin-A Cream 0.1% 20 gm
1824 tubes Retin-A Gel 0.01% 15 gm
U.S. MFGR., DATE OF EXPORT:
Armour - Aquasol;
Abbott - Enduron, Iberet-Folic;
Marion - Pavabid;
Ortho - Retin-A
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Room 1005 Sutherland House, 3 Charter Road Central,
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: Invoice is only document.

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FDA SAMPLE #: 436026
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252683-2
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/24/85
VALUE: $83,867
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Nitro-Bid, Debrox and Gly-Oxide released, others detained - document review only
MEDICATION: 3096 bottles Nitro-Bid Caps 2.5 mg 100's
6624 bottles Debrox Drops 15 ml
4694 bottles Gly-Oxide liquid 15 ml
3624 bottles Gly-Oxide liquid 60 ml
240 dozen Correctol Laxatives 30's
108 dozen Preparation H Ointment 1 oz
72 dozen Preparation H Ointment 2 oz
72 dozen Preparation H Suppositories 12's
48 dozen Preparation H Suppositories 24's
96 dozen Anacin Tabs 50's
96 dozen Dristan Tabs 24's
120 Freezone Corn Remedy 0.31 oz
U.S. MFGR., DATE OF EXPORT:
Marion - Nitro-Bid, Debrox, Gly-Oxide;
Schering Plough - Correctol;
Whitehall - Preparation H, Anacin, Dristan, Freezone
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Returned by ocean freight.
(2) Some over-the-counter products included.
(3) Invoice is the only document.

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FDA SAMPLE #: 436046
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252691-0
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/18/85
VALUE: $145,593
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 4800 bottles Lens Lubricant 0.5 oz
9600 bottles Daily Cleaner 1.5 oz
7200 bottles Sensitive Eyes Saline 237 ml
12,000 bottles Sensitive Eyes Saline 355 ml
10,000 bottles Visine Eye Drops 355 ml
U.S. MFGR., DATE OF EXPORT: Bausch and Lomb;
Pfizer for Visine.
EXPORTER TO U.S.: Satim Pharmacare,
141 Cecil Street, #07-07, Singapore 0106
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Detained on importer's premises.
(2) Over-the-counter products.
(3) Returned to the U.S. by ocean freight.

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FDA SAMPLE #: 436047
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252692-3
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/27/85
VALUE: $42,286
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 4000 tubes Preparation H Ointment 1 oz
6000 boxes Naturacil Chewable 24's
U.S. MFGR., DATE OF EXPORT: Whitehall -
Preparation H;
Mead Johnson - Naturacil
EXPORTER TO U.S.: Satim Pharmacare
141 Cecil Street #07-07, Singapore 0106
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Returned to U.S. by ocean freight.
(2) No record of Hong Kong connection - invoice (only document) suggests Singapore to Miami.
(3) Sona has several Miami addresses, goods shipped to 2315 N.W. 107th Avenue S. #20, the Miami Free Zone.
(4) Over-the-counter products.

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FDA SAMPLE #: 436048
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252690-7
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/27/85
VALUE: $119,047
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 600 bottles Aquasol A Caps
50,000 in 100's
3000 bottles Nicobid Temps 125 mg 100's
4000 bottles Nicobid Temps 250 mg
U.S. MFGR., DATE OF EXPORT:
Armour - Aquasol
USV - Nicobid
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: Invoice is only document.

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FDA SAMPLE #: 436439
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-313194-1
REIMPORTER: Mi-Scott International
4300 SW 73rd Avenue
Miami, Florida 33155
REIMPORTATION DATE: 2/25/86
VALUE: $54,994
UNLOADING PORT: Port Everglades, Florida
ENTRY PORT: Port Everglades, Florida
EXPORT PORT: Rotterdam, Holland
STATUS: Detained - document review only
MEDICATION: 4086 dozen over-the-counter products: Gynecort, Lanacane, Vagisil, Grecian Formula, Johnson's Foot Soap, Odor-Eaters, Lanacort
U.S. MFGR., DATE OF EXPORT: Combe, 12/85
EXPORTER TO U.S.: Imsurex
Schipmolen 7, 1035 CE Amsterdam, Holland
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Certificate from Rajen Pahladsingh.
(2) Imsurex headquarters are in Surinam with branch office in Guyana.
(3) Country of origin noted as France and U.K., as well as the United States.

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FDA SAMPLE #: 436444
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-198038-9
REIMPORTER: Mi-Scott International
4300 SW 73rd Avenue
Miami, Florida 33155
REIMPORTATION DATE: 2/26/86
VALUE: $53,713
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Curacao, Netherlands Antilles
STATUS: Detained - document review only
MEDICATION: 2030 cases of over-the-counter products, including Gynecort, Lanacane, Lanacort, Vagisil, Johnson's Foot Powder and Grecian Formula.
U.S. MFGR., DATE OF EXPORT: Combe
EXPORTER TO U.S.: G.V. Freezone N.V.
P.O. Box 442, Curacao, N.V.
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) List of products virtually identical to FDA Sample # 436439.
(2) Declared value $256,360, but itemized invoiced at $53,713.

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FDA SAMPLE #: 513988
FDA DISTRICT: Los Angeles, California
CUSTOMS ENTRY #: 86-500744-2
REIMPORTER: K.L.F. International, Inc.
25 W. Thomas, Phoenix, Arizona 85013
REIMPORTATION DATE: 11/29/85
VALUE: $25,000
UNLOADING PORT: Los Angeles, California
ENTRY PORT: Phoenix, Arizona
EXPORT PORT: Manila, Philippines
STATUS: Released - incomplete document review - 12/3/85
MEDICATION: 398 bottles Medrol 4 mg 100's
500 boxes Neo-Synephrine 1 ml x 25 ampules
U.S. MFGR., DATE OF EXPORT:
Neo-Synephrine - Winthrop Pharmaceuticals
Medrol - Upjohn
EXPORTER TO U.S.: J.W.S. Trading
4075 Airport Road, Baclaran, Paraaque,
Metro Manila, Philippines
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Winthrop - Sterling Products International, Inc., Manila, Philippines, 9/20/85;
Upjohn and Winthrop - Mercury Drug Corporation, Libis, Quezon City, Philippines, date not available.
NOTES: (1) Charlie Moss, FDA Phoenix, in transmittal slip to L.A., says "Reason for Return: This wholesaler buys overstock from foreign sources and resells in U.S. He intends to do more of this and wants to comply with our requirements. Please expedite."
(2) Letter dated May 5, 1985 from Rollin Tusalem, Jr., Marketing Director, Winthrop Pharmaceuticals (Philippines) -- "To Whom It May Concern .... Neo-Synephrine is a product imported from Winthrop Laboratories, ... New York, USA. This certification issued at the request of Mercury Drug of Sucat, Paranaque, Metro Manila" -- four months prior to invoice supplied to FDA.
(3) Letter of August 21, 1985 from Serafin Panganiban, Marketing Manager, Upjohn (Philippines) to Mercury Drug certifies "720 bottles of Medrol Tab 4 mg with Lot No. 790RS expiring Dec. 1989 you have purchased from Upjohn, Inc. Philippines per Invoice 40064 dated

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July 1, 1985 were made in the United States." The "S" in 790RS is circled and handwritten "Typo. error should be F" inserted.
(4) No documentation of export from U.S. and letters (one with inconsistent date) only evidence of sale to Mercury Drug, and no documentation of sale from Mercury to J.W.S. Trading.

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FDA SAMPLE #: 525580
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: 85-190735
REIMPORTER: Norman Goldstein
21 Nelson Avenue
Hicksville, New York
REIMPORTATION DATE: 7/17/85
VALUE: $51,902
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: Philadelphia, Pennsylvania
EXPORT PORT: Rotterdam, Holland
STATUS: Detained - document review only
MEDICATION: 440 dozen Allerest
330 dozen CaldeCORT
440 dozen Caldesene
770 dozen Cruex
1320 dozen Desenex
220 dozen Sinarest
110 dozen Ting
110 dozen Fresh Roll-on
U.S. MFGR., DATE OF EXPORT: Penwalt, 3/28/85
EXPORTER TO U.S.: Unknown
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Sold to: Mr. Claude Socroun, Chairman of the Board, A.F.T. International Corporation, 48-52 Glenwood Street, Little Neck, New York;
(2) Shipped to: Societe Vimaud, Dakar, Senegal.
NOTES: (1) "For the account of" Allou Distributors, 50 Emjay Boulevard, Brentwood, New York 11717.
(2) 10 percent additional merchandise invoiced at "no charge" with a 37 percent overall discount applied at the end in the Penwalt invoice.
(3) Only document besides the FDA Form 701 is the Penwalt invoice.

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FDA SAMPLE #: 525674
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: 86-240409-3
REIMPORTER: National Business Enterprises
One Bala Cynwyd Suite 432
Bala Cynwyd, Pennsylvania 19004
REIMPORTATION DATE: 10/9/85
VALUE: $33,000
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: Philadelphia, Pennsylvania
EXPORT PORT: Manila, Philippines
STATUS: Detained - document review only
MEDICATION: 2200 bottles Medrol 4 mg 100's
U.S. MFGR., DATE OF EXPORT: Upjohn, 3/5/86
EXPORTER TO U.S.: Medic's International
Suite 7-A, Vernida Condominium, Adelantado Street,
Makati, Metro Manila, Philippines, 10/7/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Slalair Express, Inc., 127 E. Rodriguez Avenue, Quezon
City, Philippines, 10/3/85
NOTES: Order placed 2/15/86 by
Upjohn (Philippines) - pro forma invoice is for 5760
bottles.

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FDA SAMPLE #: 525680
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: 85-131059-6
REIMPORTER: National Business Enterprises
REIMPORTATION DATE: 9/23/85
VALUE: $31,157
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: New York, New York
EXPORT PORT: Guam
STATUS: Detained - document review only
MEDICATION: 1500 pieces Komed H.C.
4320 pieces Eppy 1%
5230 pieces Fluress
U.S. MFGR., DATE OF EXPORT: Barnes-Hind, 8/26/85
EXPORTER TO U.S.: Unknown
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Reimporter invoice letterhead is illegible, as is address on Barnes-Hind export packing list (only documents supplied besides incomplete FDA Form 701).
(2) Barnes-Hind export packing list includes 3 other items and larger quantities.

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FDA SAMPLE #: 525730
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: Unknown
REIMPORTER: National Business Enterprises
REIMPORTATION DATE: 10/11/85
VALUE: $124,469
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: Philadelphia, Pennsylvania
EXPORT PORT: Agana, Guam
STATUS: Unknown
MEDICATION: 4104 pieces Fluress 5 ml
5760 pieces Eppy/N 1% 7.5 ml
1584 pieces Eppy/N .5% 7.5 ml
2928 pieces Komed HC 1.75 Fl Oz
8568 pieces Komed Regular 1.75 Fl Oz
11,136 pieces Degest 2 15 ml
6528 pieces Lyteers 15 ml
1532 pieces Blinx 120 ml
2304 pieces Komex 75 gr
6048 pieces Soft Mate 30 ml
1969 pieces Soft Mate 15 ml
U.S. MFGR., DATE OF EXPORT: Barnes-Hind,
9/30/85, 8/7/85, 7/25/85
EXPORTER TO U.S.: Azalea International
Trading Corporation, P.O. Box 23062 BMF, Agana, Guam
96921
OTHER FOREIGN HANDLERS, RECEIPT DATES: Azalea
International Trading Corporation, DITC Building,
Tamuning, Guam 96910
NOTES: (1) Not on FDA computer.
(2) Several addresses in Guam used by Azalea on
different Barnes-Hind invoices.

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FDA SAMPLE #: 525746
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: 86-242458-1
REIMPORTER: National Business Enterprises
REIMPORTATION DATE: 10/25/85
VALUE: $45,504
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: Philadelphia, Pennsylvania
EXPORT PORT: Manila, Philippines
STATUS: Detained - document review only
MEDICATION: 9480 bottles Provera 10 mg (25's)
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: Medic's International, Manila, Philippines
OTHER FOREIGN HANDLERS, RECEIPT DATES: Upjohn (Philippines)
NOTES: Commercial documents largely illegible.

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FDA SAMPLE #: 525861
FDA DISTRICT: Philadelphia, Pennsylvania
CUSTOMS ENTRY #: 86-242458-1
REIMPORTER: National Business Enterprises
One Bala Cynwyd Plaza, Suite 432
Bala Cynwyd, Pennsylvania 19004
REIMPORTATION DATE: 12/24/85
VALUE: $10,128
UNLOADING PORT: Philadelphia, Pennsylvania
ENTRY PORT: Philadelphia, Pennsylvania
EXPORT PORT: Tokyo, Japan
STATUS: Unknown - see notes
MEDICATION: 19 cartons, 6624 pieces Degest 2
U.S. MFGR., DATE OF EXPORT: Barnes-Hind, 10/30/85
EXPORTER TO U.S.: Antonio L. Almendras
Agana Shopping Center, Agana, Guam 96911, 12/16/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Azalea International Trading Corporation, DITC Building, Ground Floor, Tamuning, Guam, 12/9/85
NOTES: (1) FDA computer says detained, document review only; however, Release Notice dated 1/7/86 signed by Eleanor A. McCarron says "Release with Comment. These are American Goods Returned. Entire shipment was returned due to over-surplus. The products' code, expiration date, and new drug status have been verified."
(2) Shipping documents indicate Tokyo was only an intermediate point. Port of origin was Guam.
(3) Initial invoice, Barnes-Hind to Azalea was for large order of Eppy/N, Hypersal, Degest, Fluress, and other contact lens related solutions.
(4) Joe Del Grosso is National Business Enterprises contact.

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FDA SAMPLE #: 574052-5
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-367172-5
REIMPORTER: Trevor F. Maingot
29 Willcher Drive
St. Catherine's, Ontario, Canada
REIMPORTATION DATE: 8/17/85
VALUE: $31,411
UNLOADING PORT: Miami, Florida
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Antigua, British West Indies
STATUS: Released - physical samples analyzed
MEDICATION: 180 Lincocin Caps 100's
432 Tolinase 250 mg 200's
312 Tolinase 250 mg 100's
281 Cleocin Caps 100's
U.S. MFGR., DATE OF EXPORT: Upjohn, 7/29/85
EXPORTER TO U.S.: Hutchinson (Antigua) Ltd.
P.O. Box 1048, St. John's, Antigua
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Laboratory analysis shows within USP limits.
(2) Uniformity of dose units, dissolution and water tests were all satisfactory.
(3) Hutchinson certifies that goods left Puerto Rico on 7/29/85.
(4) Hutchinson stationery says "importers, exporters and manufacturers representatives."
(5) Upjohn (Inter American) invoice also contains Provera, Trobicin, Motrin, and Cleocin Palmitate.
(6) Comparative prices: export unit prices $14.05, $7.25, $32.92 and $32.45; reimport unit prices: $21.91, $11.75, $39.50 and $39.89.

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FDA SAMPLE #: 574064-5
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-483548-9
REIMPORTER: Arthur Weitzman
c/o Limax Wholesaler
35 Doyle Court
East Northport, New York 11731
REIMPORTATION DATE: 8/11/85
VALUE: $291,563
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: London, England
STATUS: Released - physical sample analyzed
MEDICATION: 4000 Minocin 100's
4000 Minocin 50's
U.S. MFGR., DATE OF EXPORT: Lederle
(Cyanamid International), 7/25/85
EXPORTER TO U.S.: InterTrading S.A.R.L.
Macarius Street 14, Limassol, Cyprus, 8/5/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Mercury S.A.L., P.O. Box 11-515, Beirut, Lebanon,
undated
NOTES: (1) Invoice InterTrading to Limax
for $311,000.
(2) Lena Lederman, Vice President of Limax, writes to
FDA on 9/24/85, "We purchase surplus on overstocked
merchandise."
(3) No shipping documents, Lebanon to Cyprus, Cyprus
to London.
(4) Redelivery ordered by Customs on 12/30/85 -- FDA
had released 10/21/85.
(5) Samples meet USP specifications.
(6) "There was some indication that drugs may not have
been in their original containers (i.e. Minocin
capsule containers had no cotton plugs or cellophane
seals). Copies of invoices for the Squibb and Lilly
drugs indicate costs substantially below the wholesale
costs listed in the 1985 Red Book (40-50 percent of
wholesale). 8/14/85 FDA memo from Willis Cobb, Jr. --
Customs had singled out this and two other shipments
for FDA's particular attention: (1) Entry No.
85-487849-1 Galaxy to Rx Wholesaler (Ceclor); and (2)
FDA # 574072 Squibb drugs to Maingot for H.L. Moore
(Corgard, Mycostatin Vaginal Tabs, and Velosef).

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(7) 8/26/85 - Lederle (White Plains), "said these were (illegible) without plugs or seals."

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FDA SAMPLE #: 574072
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-366832-7
REIMPORTER: Trevor F. Maingot
29 Willcher Drive
St. Catherine's, Ontario, Canada
REIMPORTATION DATE: 8/7/85
VALUE: $10,900
UNLOADING PORT: Miami, Florida
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Grand Cayman Island
STATUS: Refused entry - document review only
MEDICATION: 148 Corgard 40 mg 100's
80 Corgard 80 mg 100's
16 Corgard 80 mg 1000's
36 Mycostatin Ointment 30 gm
36 Mycostatin Top PWD 1/2 oz
30 Mycostatin Oral Tabs 100's
96 Mycostatin Vaginal Tabs 15's
20 Velosef Caps 250 mg 100's
20 Velosef Caps 500 mg 100's
U.S. MFGR., DATE OF EXPORT: Squibb,
date unknown
EXPORTER TO U.S.: Miller's Pharmacy
P.O. Box 48, Grand Cayman Island
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Letter from W.N. Proctor Company (broker) dated 9/20/85 to FDA states, "through some confusion" shipment was released by U.S. Customs (8/14/85) and shipped to H.L. Moore. FDA investigative report dated 8/26/85 states that visit to H.L. Moore found some Squibb merchandise mixed with other lot numbers in warehouse. Most merchandise had been sold to retail customers, according to Gerald Rome who said he was unaware of detention order. "Mr. Rome went on to state that shipment invoices covering products from H.L. Moore to their various accounts also do not list lot numbers of the products." (emphasis added).
(2) Trevor Maingot operates as Universal Sales, according to Mr. Rome.
(3) Notice of Refusal of Admission issued by FDA on 10/1/85. Redelivery ordered 12/23/85 by Customs. No documents indicate how much product, if any, was

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recovered or how it was disposed of, or explain lag in FDA and Customs action. Handwritten notes indicate possible bond action, no formal documents in FDA files.
(4) Proctor letter states that "Consignee (Maingot) has had 30 to 40 shipments through Boston in the last eighteen (18) months..."
(5) Telephone conversation memo with Maingot dated 1/31/85 states that he claims six shipments of drugs through Boston to be "Over-stock of Squibb and Upjohn manufactured in USA from Antigua and Curacao." Maingot does not take possession of the goods after importation, "they are forwarded to several firms in the New York area." (emphasis added). Listed firms are Quality King, Victoria Sales and H.L. Moore.

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FDA SAMPLE #: 574132
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-368952-6
REIMPORTER: Trevor F. Maingot
29 Willcher Drive
St. Catherine's, Ontario, Canada
REIMPORTATION DATE: 9/6/85
VALUE: $17,347
UNLOADING PORT: Miami, Florida
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Castries, St. Lucia
STATUS: Released - physically analyzed
MEDICATION: 42 Corgard Tabs 40 mg 100's
30 Corgard Tabs 80 mg 100's
18 Corgard Tabs 80 mg 1000's
30 Corside Tabs 40 mg 100's
74 Corside Tabs 80 mg 100's
12 Halog Ointment 0.1% 15 gm
24 Mycostatin Cream 30 gm
18 Mycostatin Ointment 30 gm
54 Mycostatin Tabs 100's
60 Theragran Hematinic Tabs 90's
120 Velosef Caps 250 mg 24's
108 Velosef Caps 250 mg 100's
66 Velosef Caps 500 mg 100's
48 Velosef Caps 500 mg 24's
U.S. MFGR., DATE OF EXPORT: Squibb, 8/5/85
EXPORTER TO U.S.: Renwick and Company, Ltd.
19 Bridge Street, Castries, St. Lucia
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Location of lot listed as Victoria Sales, 541 West 21st Street, New York, New York, with notation "Freight now at Eastern - Boston."
(2) 10/1/85 Maingot telex explains that he is a broker importing U.S. goods returned "because of prices and discounts offered to me."
(3) 10/22/85 R. Hooper at Squibb writes FDA, "All control numbers ... were verified .... However, not all products were shipped as export."
(4) Released by Customs on 9/10/85.
(5) 11/6/85 letter from Maingot to Kravchuk (FDA Boston), "This warrant indicates that my shipment .... your Doc. # 574132, was in fact held in (St. Lucia) government bonded warehousing, upon its arrival from

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Puerto Rico, and until its departure for Boston."

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FDA SAMPLE #: 574142
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-487184-1
REIMPORTER: Victoria Sales
541 West 21st Street
New York, New York 10011
REIMPORTATION DATE: 9/12/85
VALUE: $10,722
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Bremen, West Germany
STATUS: Released - document sample only, documents incomplete
MEDICATION: 4896 bottles Bufferin 100's
U.S. MFGR., DATE OF EXPORT: Bristol-Myers, date not available
EXPORTER TO U.S.: Kaufring Aktiengesellschaft
Neugasse 29 CH-6301 ZUG, Schweiz
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Documents incomplete.
(2) Victoria Sales (Mark Feld) letter to FDA: "This merchandise were [sic] shipped from Bristol-Myers USA to Hong Kong agent, then shipped from Hong Kong to West Germany to our supplier. Our supplier send [sic] goods to us through BCR HELENE (vessel name)."
(3) Bristol-Myers told FDA shipment was intended for Singapore.
(4) Customs ordered redelivery on 2/13/86.
(5) Victoria Sales letter to FDA 9/11/85, "We do not have any additional documents available, please labitory [sic] test merchandise to proof [sic] that its [sic] authentic."
(6) 2/19/86 FDA note states no laboratory work done.
(7) FDA obtained package and lot numbers and expiration dates from Victoria Sales by telephone on 12/6/85 and confirmed with Bristol-Myers by telephone.
(8) Memorandum of phone conversation between Larry Roth (Attorney for Victoria Sales) and Kravchuk (FDA), "Attorney Roth stated he believes FDA has overstepped our authority by requiring his client to provide confidential information required under import alert. Attorney Roth stated his client's release of such information may result in the various drug manufacturers learning of his client's sources of

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products."

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FDA SAMPLE #: 574148
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-488629-2
REIMPORTER: Victoria Sales (consignee)
New York, New York
REIMPORTATION DATE: 9/7/85
VALUE: $76,380
UNLOADING PORT:
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: England
STATUS: Released - physical sample analyzed
MEDICATION: Ceclor 250 mg.
U.S. MFGR., DATE OF EXPORT: Eli Lilly
EXPORTER TO U.S.: Oscar Pharmaceuticals
304 Orchard Road, Singapore
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Laboratory analysis only.
(2) Laboratory analysis and visual observations conclude Ceclor is genuine.
(3) Customs ordered redelivery on 2/3/86. FDA Boston (Kravchuk) released 10/31/85.
(4) After FDA release, some 500 mg Ceclor sold to International Cosmetics Division, H.L. Moore Company, 45 Peter Court, New Britain, Connecticut, apparently by Northside Development, Inc., doing business as J. Dekama Associates, and Salla Beauty Laboratories, Suite 100, 12 Route 17 North, Paramus, New Jersey 07651. Dekama never took title or even saw the goods.
(5) Oscar invoice to New Britain (Connecticut) National Bank, c/o Victoria Sales.
(6) See Note 8, FDA Sample # 574142.
(7) 10/25/85 Feld (Victoria Sales) writes Kravchuk (FDA) to "voluntarily request for the FDA to refuse admittance to the above shipment. As we are going to export the above shipment to: Oscar Pharmaceuticals ..." ("Above shipment" includes FDA Sample # 574180). 10/31/85 FDA called Victoria Sales and told them the laboratory analysis was okay, would permit entry
(8) Contains various lot numbers - #7PL94C was to expire 10/1/85.
(9) No paper trail, Lilly to Oscar.

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FDA SAMPLE #: 574149
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-488602-7
REIMPORTER: Victoria Sales
541 West 21st Street
New York, New York 10011
REIMPORTATION DATE: 9/8/85
VALUE: $41,100
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Brussels, Belgium
STATUS: Released - document review only
MEDICATION: 9500 pieces Eppy/N 1%
4500 pieces Eppy/N 0.5%
U.S. MFGR., DATE OF EXPORT: Barnes-Hind, 8/26/85
EXPORTER TO U.S.: Oridan Trading, Ltd.
Postfach 146, 9493 Mauren, Im Ziel 430, Buchs (Kt. St. Gallen, Schweiz)
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Bromex Trading, Ltd., c/o Pragent, Washingtonova 17, 11000 Prague 1, Czechoslovakia
NOTES: (1) Barnes-Hind Export, Inc. sold 9500 of each to Bromex.,
(2) No shipping documents, Prague to Brussels, no sales documents Bromex to Oridan.
(3) See Note 8, FDA Sample # 574142.
(4) Product identification data provided to FDA by letter -- no physical inspection.
(5) Victoria Sales letter says goods shipped from Prague to Brussels but no records provided.

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FDA SAMPLE #: 574150
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-483626-8
REIMPORTER: Arthur Weitzman
c/o Limax Wholesaler
35 Doyle Court
East Northport, New York 11731
REIMPORTATION DATE: 9/12/85
VALUE: $77,750
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: London, England
STATUS: Released - physical sample taken
MEDICATION: 1000 Minocin Caps 50 mg 100's
1000 Minocin Caps 100 mg 50's
U.S. MFGR., DATE OF EXPORT: Lederle
(Cyanamid International), 7/30/85
EXPORTER TO U.S.: InterTrading S.A.R.L.
Macarius Street 14, Limassol, Cyprus, 8/28/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Mercury S.A.L., P.O. Box 11-515, Beirut, Lebanon
NOTES: (1) Broker is Magic Customs Broker
but bill of lading states that consignee is
InterTrading, c/o Neptune Traffic, 395 Maverick
Street, Suite 214, Boston, Massachusetts, and issuing
agent is Cyprus Trade and Tours, Nicosia.
(2) British Airways document indicates direct shipment
Limassol, Cyprus to Boston.
(3) No shipping documents Lebanon to Cyprus. Goods
shipped by Rosemary Domanski, export agent, Concordia
International Forwarding for Cyanamid International
Sales Corporation, to Larnaca Airport in Cyprus, no
evidence of physical shipment to Lebanon.

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FDA SAMPLE #: 574161
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-48427-8
REIMPORTER: Rx Wholesale Supply
P.O. Box 561703
Miami, Florida 33156
REIMPORTATION DATE: 9/3/85
VALUE: $76,293
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Paris, France
STATUS: Released - no physical sample
MEDICATION: 420 Coumadin Tabs 2.5 mg 100's
2520 Coumadin Tabs 5 mg 100's
2520 Symmetrel 100 mg 100's
U.S. MFGR., DATE OF EXPORT: Du Pont Pharmaceuticals, 6/24/85
EXPORTER TO U.S.: Ronidaz International Corporation
P.O. Box 218, 1211 Geneve 11, Switzerland
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Transimpex, Bul. Skobelev 5, Sofia, Bulgaria, 7/19/85;
(2) Amiran Ben-Yemini, c/o Israel Container Line, Poststrasse 36, 2000 Hamburg 36, B.R.D., date not available;
(3) Ronidaz International, date not available;
(4) Marc Air International, 8 Rue Des Deux Cedres - B.P. 10377, 06 Charles de Gaulle Airport, Paris, date not available.
NOTES: (1) Export from Du Pont made to Mersant International, Ltd./Agents, Jamaica, New York, and payment made to order of Bulgarian Foreign Trade Bank - payment of $58,871.40 required for release.
(2) "Diversion contrary to U.S. law prohibited."
(3) Documents from Amiran Ben-Yemini to Ronidaz to Marc Air are missing.
(4) Letter from Sandler and Travis (1/2/86), attorneys for Rx Wholesale, encloses documents showing goods were shipped to the Bulgarian Foreign Trade Bank in Sofia, Bulgaria, sold by Transimpex, the Bulgarian Foreign Trade Organization to Ben-Yemini, "moved by truck from Bulgaria" to Paris and then shipped to the U.S.

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FDA SAMPLE #: 574162
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-488397-8
REIMPORTER: Rx Wholesale Supply
Miami, Florida
REIMPORTATION DATE: 8/26/85
VALUE: $115,500
UNLOADING PORT: Chicago, Illinois
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Singapore
STATUS: Seized - counterfeit
MEDICATION: 700 pieces Ceclor 250 mg
U.S. MFGR., DATE OF EXPORT: Labeled as "Eli Lilly" product
EXPORTER TO U.S.: Galaxy International
6-G, 3-5 Minden Row, Kowloon, Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Singapore certificate of origin for 500 mg Ceclor only. Customs documents show exporter is Multi Pharmaceutical Company, 2 Soon Wing Road, #07-C3 Soon Wing Industrial Building, Singapore 1334; consignee is Marc Air International; country of final destination is France. Mentions only 500 mg, 1000 bottles of 100's, 6 cartons. Note typed on certificate of origin: "Z.V. Paris," apparently refers to Zeeve Vigdor. The 500 mg from Singapore to Paris on June 29, 1985 consolidated with 250 mg Ceclor for Galaxy shipment to U.S. in August 1985. No documentation on shipment from Paris back to Singapore or Hong Kong.
(2) See also FDA Sample # 574162 - split sample - value covers both.
(3) Rx Wholesale imported for delivery to Quality King, Deer Park, New York.

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FDA SAMPLE #: 574175
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-488397-8
REIMPORTER: Rx Wholesale Supply
Miami, Florida
REIMPORTATION DATE: 8/26/85
VALUE: $115,500
UNLOADING PORT: Chicago, Illinois
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Singapore
STATUS: Seized - counterfeit
MEDICATION: 700 pieces Ceclor 500 mg
U.S. MFGR., DATE OF EXPORT: Labeled as
"Eli Lilly" product
EXPORTER TO U.S.: Multi Pharmaceutical Company,
Singapore
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Shipped by Multi Pharmaceutical Company, Singapore to Paris, Marc Air International, June 29, 1985, 1000 bottles of 100's. Note on Singapore certificate of origin: "Z.V. Paris," apparently refers to Zeeve Vigdor.
(2) Part of shipment by Galaxy on August 26, 1985 to the United States. No paper in FDA file on how 500 mg Ceclor got from Paris to Singapore for Flying Tiger shipment to Chicago.
(3) See also FDA Sample # 574162 - Ceclor split sample - value covers both.

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FDA SAMPLE #: 574180
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-488629-2
REIMPORTER: Victoria Sales
541 West 21st Street
New York, New York 10011
REIMPORTATION DATE: 9/7/85
VALUE: $76,380 total, 500 mg value is $42,330
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: England
STATUS: Released - physical sample analyzed
MEDICATION: Ceclor 500 mg
U.S. MFGR., DATE OF EXPORT: Eli Lilly
EXPORTER TO U.S.: Oscar Pharmaceuticals
304 Orchard Road, Singapore
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) FDA laboratory analysis found sample to be genuine.
(2) See FDA Sample # 574148.

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FDA SAMPLE #: 574181
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-488426-5
REIMPORTER: Rx Wholesale Supply
Miami, Florida
REIMPORTATION DATE: 8/31/85
VALUE: $215,618 total; $73,200 250 mg Ceclor;
$134,400 500 mg Ceclor.
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Paris, France
STATUS: Detained - analysis ordered - seized
MEDICATION: Sparine (Promazine HCL) Tabs
250 mg Ceclor
U.S. MFGR., DATE OF EXPORT:
Wyeth - Sparine;
Eli Lilly - Ceclor
EXPORTER TO U.S.: Ronidaz International Corporation
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Broker is Liberty International.
(2) Ceclor manufactured by Lilly in Puerto Rico, shipped to J.L. Morison, Petaling Jaya, Malaysia on July 20, 1985. Lot 9BQ56A, 250 mg, and Lot 8TS12B, 500 mg.
(3) Ronidaz invoice to Rx Wholesale - 600 bottles 250 mg Ceclor, 600 bottles 500 mg Ceclor. From Paris via Air France.
(4) Seized, contained counterfeit codes.
(5) Wyeth product code is valid, indicates manufactured in Melborne facility.
(6) See FDA Sample # 574182.
(7) Sparine listed on FDA computer as FDA Sample # 574181-A.

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FDA SAMPLE #: 574182
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-488426-5
REIMPORTER: Rx Wholesale Supply
Miami, Florida
REIMPORTATION DATE: 8/31/85
VALUE: $215,618 total; $134,000 500 mg Ceclor
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Paris, France
STATUS: Seized - counterfeit
MEDICATION: Ceclor 500 mg
U.S. MFGR., DATE OF EXPORT: Eli Lilly
(counterfeit)
EXPORTER TO U.S.: Ronidaz International Corporation
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown by documents
NOTES: (1) Invoice also contains
2304 Sparine 25 mg -- See FDA Sample # 574181
(2) Declared as eight cartons of medical aids.
(3) Papers indicate Ceclor manufactured by Eli Lilly (Puerto Rico), shipped on July 20, 1985 to J.L. Morison, Malaysia, Lot 9BQ56A (250 mg) and Lot 8TS12B (500 mg).
(4) Papers suspect.

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FDA SAMPLE #: 574204
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-268483-6
REIMPORTER: Quality King Distributors, Inc.
1095 Long Island Avenue
Deer Park, New York 11729
REIMPORTATION DATE: 9/9/85
VALUE: $12,377
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 4524 bottles Bufferin (60's, 36's, & 100's)
3000 bottles Excedrin (36's, 12's)
U.S. MFGR., DATE OF EXPORT: Bristol-Myers
EXPORTER TO U.S.: Galaxy International
Hong Kong, 7/22/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Bristol-Myers (Hong Kong) Ltd., Vita Towers, 8th Floor, 29 Wong Chuk Hung Road, Abeerden, Hong Kong;
(2) Pope's International (Hong Kong) Ltd., Room 1004 Lap Fai Building, 6-8 Pottinger Street, Hong Kong, 7/22/85.
NOTES: (1) Over-the-counter products.
(2) K.D. Jeswani, Galaxy International to Quality King dated 10/2/85 states that goods were imported from U.S. by Bristol-Myers (Hong Kong) who sold them to Pope's International (Hong Kong) Ltd., G.P.O. Box 1239, Hong Kong -- "As so many trading companies are involved in purchasing the merchandise, we, Galaxy International, are unable to provide original export details."
(3) Letter from Maureen Kwettel, Import Manager, to Michael Kravchuk, FDA Boston, encloses photographs of packages, apologizes for "mistaken lot number."
(4) Invoice, Bristol-Myers to Pope is for 4500 (plus 1 sample) of Bufferin, not 4524.
(5) FDA gave broker permission to ship goods from Boston to Quality King 11/20/85.
(6) 11/27/85 Quality King provided lot numbers and expiration dates to FDA by letter.
(7) No documents Bristol-Myers (U.S.) to Bristol-Myers (Hong Kong), but FDA claims that Bill Fray of

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Bristol-Myers confirmed that goods were of U.S. origin.

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FDA SAMPLE #: 574246
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-364749-3
REIMPORTER: Trevor F. Maingot
REIMPORTATION DATE: 9/28/85
VALUE: $19,200
UNLOADING PORT: Miami, Florida
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Bridgetown, Barbados
STATUS: Released - document review only
MEDICATION: 3000 Valisone Cream 0.1%
3000 Valisone Ointment 0.1%
3000 Garamycin Cream 0.1%
3000 Garamycin Ointment 0.1%
U.S. MFGR., DATE OF EXPORT: Schering-Plough, 8/8/85
EXPORTER TO U.S.: Collins, Ltd.
28 Broad Street, Bridgetown, Barbados
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Invoice from Collins to Proctor (broker for Trevor Maingot) states, "past payment received in advance. Balance-remittance."
(2) Schering del Caribe invoice to Collins is for $21,063.71. Collins invoice to Proctor is for $19,200. Separate Schering invoices for additional Valisone (7/23/85) and Garamycin (7/18, 7/19/85) submitted 10/15/85 after FDA challenged the quantities.

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FDA SAMPLE #: 574403
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-112577-1
REIMPORTER: Quality King Distributors, Inc.
1095 Long Island Avenue
Deer Park, New York 11729
REIMPORTATION DATE: 10/17/85
VALUE: $31,200
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 1600 dozen Vicks Vapor Rub 3 oz
U.S. MFGR., DATE OF EXPORT: Richardson-Vicks, 4/1/85
EXPORTER TO U.S.: Galaxy International
Hong Kong, 9/26/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
John D. Hutchinson Trading Company, 7th Floor, JDH Centre, Wan Hou Street, Hong Kong, 9/11/85
NOTES: (1) Held for inspection on importer's premises in New York.
(2) Letter from K.D. Jeswani (Galaxy) to Quality King states product was exported by ocean freight on 4/1/85 to Richardson-Vicks (Far East) Ltd. (Hong Kong) who sold the goods to John D. Hutchinson Trading (Hong Kong) who sold to Galaxy.
(3) Internal Richardson-Vicks contract says, "... ultimate destination Hong Kong. Diversion contrary to U.S. law prohibited."
(4) Hutchinson sold 12,400 dozen to Galaxy.
(5) Ocean freight both ways.
(6) Internal Vicks' bill of lading states shipment to Richardson-Vicks (Far East) Ltd., c/o John D. Hutchinson Trading.
(7) FDA permitted transport to Quality King 11/20/85 after consulting Customs (Leo Collins). Lot numbers and expiration date supplied back to FDA by letter on 11/27/85.

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FDA SAMPLE #: 574444
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-270331-2
REIMPORTER: Rx Wholesale Supply
REIMPORTATION DATE: 9/17/85
VALUE: $31,500
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Hong Kong
STATUS: Refused 6/17/86 - document review only
MEDICATION: 6000 pieces Premarin Vaginal Cream
U.S. MFGR., DATE OF EXPORT: Ayerst Laboratories, 7/3/85
EXPORTER TO U.S.: Galaxy International
6-G, 3-5 Minden Row, Kowloon, Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Ayerst Laboratories (Philippines)
LN Building, 738 Shaw Boulevard, Mandaluyong, Metro Manila, Philippines
NOTES: (1) "Diversion contrary to U.S. law prohibited."
(2) Shipped to Philippines by ocean freight.
(3) Natali, Inc. (a.k.a. Rx Wholesale) listed as consignee on shipping bill.
(4) No documentation of sale from Ayerst (Philippines) to Galaxy or to Aspora Pharmaceuticals (name appears on the air waybill as shipping goods to Natali).
(5) Refused on 6/17/86
(6) Rx Wholesale asks for refusal on 2/9/86 - Customs will notify FDA of details of re-export.

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FDA SAMPLE #: 574509
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-271357-7
REIMPORTER: Victoria Sales
New York, New York
REIMPORTATION DATE: 11/22/85
VALUE: $216,240
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Zurich, Switzerland
STATUS: Released - document sample only
MEDICATION: 4800 Macrodantin 50 mg (100's)
4800 Macrodantin 100 mg (100's)
U.S. MFGR., DATE OF EXPORT: Eaton Laboratories
(Norwich Eaton), 10/18/85
EXPORTER TO U.S.: Alpha Al Khalij, Germany
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Emirates Hospital Supplies, Ltd.
P.O. Box 366 Abu Dhabi, United Arab Emirates,
10/18/85;
(2) Merchants Corporation of America
Zurich, Switzerland, 11/2/85
NOTES: (1) Latest FDA computer list
indicates goods released; however, seizure by
manufacturer has apparently occurred at Victoria
Sales. Customs released the goods 12/02/85.
(2) Invoice lists Khalij office in Dubai, United Arab
Emirates.

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FDA SAMPLE #: 574510
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-402072-1
REIMPORTER: H.L. Moore Drug Exchange
370 John Downey Drive
New Britain, Connecticut 06050
REIMPORTATION DATE: 11/15/8
VALUE: $152,518
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Antwerp, Belgium
STATUS: Released - document review only
MEDICATION: 597 Pilocar 1%
1077 Pilocar 2%
1077 Pilocar 4%
357 Pilocar 6%
237 E-Pilo 1% 10 ml
717 E-Pilo 2% 10 ml
957 E-Pilo 4% 10 ml
237 E-Pilo 6% 10 ml
11994 Vasocon A 15 ml
6341 Vasocidin 5 ml
4771 Vasocidin 10 ml
2953 Inflamase 1/8% 5 ml
3595 Inflamase Forte 1% 5 ml
U.S. MFGR., DATE OF EXPORT: CooperVision, 10/9/85
EXPORTER TO U.S.: Rothwell Enterprizes
161 Abbey Road, London NW6, England
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) CooperVision, Ltd., 371 Millbrook Road Southhampton, Hampshire SO1 OHW, United Kingdom;
(2) Forwarding and Handling Company N.V., Plantin and Moretuslei 12, B-2018 Antwerp, Belgium, 11/4/85;
(3) Burma Agents Company, Ltd., Nelson House, 58 Wimbledon Hill Road, London SW19 7PA, United Kingdom.
NOTES: (1) LEP Transport used - same as Habarx.
(2) Thornton Douglas CooperVision Pharmaceuticals (Puerto Rico) certifies that these products were sold to Burma Agents Company, Ltd., UK, dated 9/18/85.
(3) Sunil Varma, Director of Burma Agents Company, is same as Sunil Varma, Rothwell Enterprizes.
(4) Rothwell invoice to H.L. Moore is for $206,104.24 <u>less</u> 26%.
(5) Burma (Varma) paid for goods on letter of credit

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from Overseas Trust Bank, Ltd. (Hong Kong).
(6) Salvage Association (London), surveyor paid by Burma, certifies the goods at CooperVision (Southhampton) on 10/17/85.
(7) Damco Air certifies goods "has been lying in Antwerp in Customs warehouse during their transit time in Antwerp."
(8) Apparently CooperVision (Puerto Rico) sold to Burma but shipped to CooperVision (United Kingdom) which shipped to Antwerp at Burma's specification -- Burma and Rockwell have same owner (Varma) which shipped to H.L. Moore.

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FDA SAMPLE #: 574527
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-260564-3
REIMPORTER: Limis Wholesalers
91 Church Road
Morganville, New Jersey 07751
REIMPORTATION DATE: 12/5/85
VALUE: $31,800
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Manila, Philippines
STATUS: Detained - physical and document samples pending
MEDICATION: 2300 bottles Antabuse (50's)
1000 bottles Tolinase (100's)
1 box (100) Aldactone 25 mg
U.S. MFGR., DATE OF EXPORT:
Antabuse - Ayerst Laboratories, 6/13/85,
Tolinase - Upjohn, 9/16/85
Aldactone - Searle (?)
EXPORTER TO U.S.: Three C's Industry
Manila, Philippines
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Ayerst - Ayerst Laboratories (Philippines), Inc. Manila, Philippines, 6/13/85;
Upjohn - Upjohn, Inc., Manila, Philippines, date not available.
NOTES: (1) Antabuse and Tolinase sent by ocean freight.
(2) Antabuse part of larger invoice including Dermoplast, Estradurin, Larylgan Throat Spray, Premarin Vaginal Cream, Thiosulfil-A Forte, Isordil, Premarin Tabs, Riopan Swallow Tabs.
(3) Limis Wholesalers also has Boston address -- Limis Wholesalers, Neptune Traffic Services, Ltd., 395 Maverick Street, Suite 214, Boston, Attention: Phil Salmon, General Manager. See also Limax Wholesalers, c/o Tradex America, same address, Attention: Phil Salmon.
(4) Tolinase part of 5000 bottle shipment.
(5) No documents Ayerst and Upjohn to Three C's Industry.
(6) Upjohn invoice #43524 is dated 11/29/85 rather than 11/22/85 as provided on 3 C's Industry's copy.

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Also, Upjohn records indicate Tolinase sold to City Drug Mart, not 3 C's.

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FDA SAMPLE #: 574541
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-256636-8
REIMPORTER: N.E. Pharmaceuticals
1320 Old Mammoth Road
Manchester, New Hampshire
REIMPORTATION DATE: 12/8/85
VALUE: $540
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: London, England
STATUS: Refused entry - recalled
MEDICATION: 50 bottles of Valium 2 mg (100's)
200 bottles of Valium 5 mg (100's)
50 bottles of Valium 10 mg (100's)
U.S. MFGR., DATE OF EXPORT: Hoffman La Roche,
date not available
EXPORTER TO U.S.: McNaughton Sales
19 Comrie Street, Crieff, Scotland
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Value seems very low.
(2) Controlled substance.
(3) Being held on importer's premises.
(4) Customs ordered redelivery on 5/14/86.
(5) New England Pharmaceuticals is a division of American Surgicare, Inc.
(6) New England Pharmaceuticals recalled drugs from its sole customer, Gosselin Pharmacies, 131 Armory Street, Manchester, New Hampshire. Recall also involved FDA Sample # 574080 and "second shipment which arrive [sic] in November" (this shipment was a sample).
(7) All recovered imported pharmaceuticals, exported by N.E. Pharmaceuticals to the United Kingdom on 5/3/86 (to Harold Mitchell and Company, Boucher Road, Belfast, Northern Ireland BT12 6QS).
(8) Valium was <u>manufactured in England</u> and was illegal to enter but not declared as American Goods Returned.

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FDA SAMPLE #: 574616
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-368656-4
REIMPORTER: Trevor F. Maingot
29 Willcher Drive
St. Catherine's, Ontario, Canada
REIMPORTATION DATE: 12/22/85
VALUE: $33,502
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Antigua, British West Indies
STATUS: Released - no physical sample
MEDICATION: 350 pieces Tolinase 250 mg Tabs 100's
480 pieces Tolinase 250 mg Tabs 200's
296 pieces Cleocin HCL 150 mg Caps 100's
180 pieces Lincocin 500 mg Caps 100's
U.S. MFGR., DATE OF EXPORT: Upjohn, 11/5/85
EXPORTER TO U.S.: Hutchinson (Antigua) Ltd.
St. John's, Antigua
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Location of lot for FDA examination noted as "H.L. Moore, 370 John Downey Drive, New Britain, Connecticut."
(2) See Note 4 FDA Sample # 574841.
(3) Redelivery ordered by Customs 5/14/86.
(4) Upjohn invoice to Hutchinson also includes Provera and Kaopectate.
(5) Sold to Maingot on 11/20/85.
(6) Upjohn confirmed that lot numbers were okay.

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FDA SAMPLE #: 574632
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-260657-4
REIMPORTER: Limax Wholesalers
200 Avenue B
Bayonne, New Jersey C7002
REIMPORTATION DATE: 12/26/85
VALUE: $67,050
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Manila, Philippines
STATUS: Detained - physical and document sample pending
MEDICATION: 4500 bottles Medrol 4 mg Tabs (100's)
U.S. MFGR., DATE OF EXPORT: Upjohn, 8/22/85
EXPORTER TO U.S.: Three C's Industry
Metro Manila, Philippines, 12/18/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Upjohn (Philippines), 9/28/85
NOTES: (1) Importer listed as Arthur Weiztman, c/o Limax Wholesalers.
(2) Letter from Lela Lederman, President, Limax Wholesalers.
(3) Invoice to Limax Wholesalers c/o Tradex America, 395 Maverick Street, Suite 214, Boston, Massachusetts 02128, Attention: Phillip Salmon.
(4) Invoice of Upjohn shipment to Manila included 4896 bottles of Medrol and 6000 bottles Provera Tabs.
(5) Apparently unrelated shipping manifest says 22 cartons of Tolinase 250 mg.
(6) Attached to the documentation is an apparently unrelated invoice, Ayerst (International) to Ayerst (Manila) for Antabuse, Dermoplast, Estradurin, Larylgan, Pamine, Thiosulfil, Isordil and Riopan.
(7) Invoice Three C's Industry to Limax includes "4 pcs. assorted gifts" invoiced at NC (no charge)."
(8) See Note 4, invoice Upjohn (Philippines) for 2000 bottles of 100 250 mg Tolinase tablets dated 1/30/86. Salesman Valvuena. Sold to Three C's Industry.
(9) Invoice 12/16/85, 4500 bottles of 100's Medrol 4 mg tablets, sold by Upjohn (Philippines) to Three C's Industry.
(10) See Notes 8 and 9. Upjohn telexes and copies of invoices for Philippines indicate no sales to Three

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C's Industry. They do indicate sales of other products to hospital. Upjohn says invoices are false.

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FDA SAMPLE #: 574633
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-260653-2
REIMPORTER: Limax Wholesalers
200 Avenue B
Bayonne, New Jersey 07002
REIMPORTATION DATE: 12/23/85
VALUE: $27,600
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Lagos, Nigeria
STATUS: Released - document review only
MEDICATION: 1200 bottles Minocin Caps 100 mg (50's)
U.S. MFGR., DATE OF EXPORT: Lederle, 7/3/85
EXPORTER TO U.S.: Innovation Investors, Ltd.
Plot 29 Bajulaya Road, Shomolu-Lagos, Nigeria,
12/12/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Neopharm, Ltd., 17, Yosef Karo Street, P.O.B. 7108,
Tel-Aviv, Israel
NOTES: (1) Cyanamid to Neopharm invoice is for
1238 bottles.
(2) Neopharm to Innovation invoice for the same
$27,600 as reimport price to U.S.
(3) KLM Shipping bill from Neofarm [sic] to "Investors
Limited Innovation" c/o Marc Air, Charles De Gaulle
Airport, Paris; "to be transferred to Lagos, Nigeria
by Marc Air." Marc Air may be the same firm used by
Ronidaz (Switzerland) in its diversion transactions.
Air France shipment from Innovation to Limax also
through Marc Air, BP 10377, 95706 Roissy Cedex, Paris
CDG.
(4) Released without physical sample despite five
months in Middle East and Africa.

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FDA SAMPLE #: 574645
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-260656-1
REIMPORTER: Limis Wholesalers
91 Church Road
Morganville, New Jersey 07751
REIMPORTATION DATE: 12/9/85
VALUE: $7536
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Manila, Philippines
STATUS: Released - document review only
MEDICATION: 1696 tubes Premarin Vaginal Cream Refill
504 tubes Premarin Vaginal Cream Refill
144 Secules 2 ml. Estradurin 40 mg.
U.S. MFGR., DATE OF EXPORT: Ayerst, 6/13/85
EXPORTER TO U.S.: Three C's Industry, 7/31/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Ayerst Laboratories (Philippines) Inc.
LN Building, 738 Shaw Boulevard, Mandaluyong, Metro Manila, Philippines, date not listed
NOTES: (1) Port of unloading "Boston via San Juan."
(2) Shipped to the Philippines by ocean freight (S.S. President Lincoln).
(3) Part of large invoice (6/13/85) including Antabuse, Dermoplast, Estradurin, Larylgan, Thiosulfil, Isordil and Riopan (Ayerst U.S. to Ayerst Philippines).
(4) Invoice (7/31/85) Ayerst (Philippines) to Three C's Industry includes 2388 bottles Antabuse, 1406 vials Estradurin, 2200 tubes Premarin Vaginal Cream and 1700 bottles Thiosulfil.

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FDA SAMPLE #: 574676
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 85-488647-0
REIMPORTER: Rx Wholesale Supply
REIMPORTATION DATE: 9/12/85
VALUE: $10,920
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Paris, France
STATUS: Released 1/7/86, redetained 1/8/86, and refused entry 6/17/86
MEDICATION: 3000 tubes Halog Cream 15 mg.
100 bottles Enduron Tabs 5 mg. (1000's)
U.S. MFGR., DATE OF EXPORT: Squibb; Abbott, dates unknown
EXPORTER TO U.S.: Ronidaz International Corporation
OTHER FOREIGN HANDLERS, RECEIPT DATES: (1) Marc Air International
8 Rue Des Deux Cedres - BP 10377, 06 Charles de Gaulle Airport, Paris, France, 6/9/85.
(2) Multi Pharmaceutical Company, 80 Playfair Road, #06-13 Block 8, Kapo Factory, Singapore 1336.
NOTES: (1) No physical sample. Documents do not reveal evidence of original export. Rx Wholesale (known) and Multi Pharmaceutical (suspected) of handling counterfeit Ceclor. Redetained 1/8/86 but still no physical sample.
(2) Second Multi Pharmaceutical address: 2 Soon Wing Road, #07-C3 Soon Wing Industrial Building, Singapore 1334.
(3) Rx Wholesale requested refusal 2/19/86 to re-export -- Customs will inform FDA of re-export details.

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FDA SAMPLE #: 574688
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-369040-8
REIMPORTER: Trevor F. Maingot
REIMPORTATION DATE: 1/1/86
VALUE: $30,720
UNLOADING PORT: Miami, Florida
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Bridgetown, Barbados
STATUS: Released - document review only
MEDICATION: 9600 Valisone Cream 0.1%
9600 Garamycin Ointment 0.1%
U.S. MFGR., DATE OF EXPORT: Schering-Plough, 11/11/85
EXPORTER TO U.S.: Collins, Ltd.
28 Broad Street, Bridgetown, Barbados, 11/11/85
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Trevor Maingot stationery lists him as "Export Management Consultant." Letter says, "please be advised that I carry on business as a broker, and it is in that capacity as a broker, I take the business opportunity of purchasing U.S. manufactured goods from time to time, because of prices and discounts offered to me."
(2) Manufacturer is Schering del Caribe, Inc.
(3) Invoice is to W.N. Proctor Company, Inc., 115 Broad Street, Boston, Massachusetts 02110.
(4) Collins bought Garamycin and 4800 Valisone from Schering on 11/11/85 and another 4800 Valisone on 11/25/85.

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FDA SAMPLE #: 574704
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-369481-5
REIMPORTER: Trevor F. Maingot
REIMPORTATION DATE: 1/8/86
VALUE: $14,602
UNLOADING PORT: Miami, Florida
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Grand Cayman Island, British West Indies
STATUS: Released - document review only
MEDICATION: 300 bottles Tolinase (200's)
300 bottles Tolinase (100's)
96 bottles Lincocin (100's)
U.S. MFGR., DATE OF EXPORT: Upjohn, 9/26/85
EXPORTER TO U.S.: Miller's Pharmacy
P.O. Box 48, Grand Cayman Island, British West Indies
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Upjohn invoice to Miller's Pharmacy is identical to submission in FDA Sample # 778550 (Orlando). Invoice for $14,769.53 (includes 4 bottles of Cleocin not resold). Total resale price - $27,951.
(2) Note says, "Delivery to: H.L. Moore, New Britain, Connecticut."
(3) 2/20/86 letter from attorneys for Maingot acknowledges inability to obtain original manufacturers' certificates and asks that manufacturers not be contacted.

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FDA SAMPLE #: 574735
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: Unclear
REIMPORTER: Victoria Sales
541 West 21st Street
New York, New York 10011
REIMPORTATION DATE: 1/10/86
VALUE: $107,000
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: London, England
STATUS: Released - document review only
MEDICATION: 10,000 bottles NegGram Caps 500 mg.
U.S. MFGR., DATE OF EXPORT: Winthrop-Breon, 11/1/85
EXPORTER TO U.S.: Alpha Al Khalij
P.O. Box 1781, Dubai, United Arab Emirates
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Shipped by ship to the
United Arab Emirates.
(2) No physical sample despite shipping route.
(3) Khalij invoice to Merchants Corporation of America
c/o a Zurich bank -- subsequently c/o Victoria Sales
typed in.

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FDA SAMPLE #: 574841
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-260833-6
REIMPORTER: Arthur Weitzman
c/o Limax Wholesalers
200 Avenue B
Bayonne, New Jersey 07002
REIMPORTATION DATE: 2/4/86
VALUE: $38,550
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Manila, Philippines
STATUS: Detained - physical and document samples pending
MEDICATION: Upjohn: 200 bottles Tolinase 250 mg.
Allergan: 1000 tubes Chloroptic Ointment S.O.P. 3.5 grams.
U.S. MFGR., DATE OF EXPORT: Upjohn (9/16/85); Allergan (undated)
EXPORTER TO U.S.: Three C's Industry
112 Levitown Avenue, Metro Manila, Philippines, 1/30/86
OTHER FOREIGN HANDLERS, RECEIPT DATES: Upjohn: Upjohn, Inc., Metro Manila, Philippines.
Allergan: Zuellig Pharma Corporation, F.E. Zuellig Building, Buendia Avenue Extension, Makati, Metro Manila, Philippines.
NOTES: (1) Invoice says: Limax Wholesalers, c/o Tradex America, 395 Maverick Street, Suite 214, Boston, Massachusetts 02128, Attn.: Phillip Salmon, Tel. # (516) 462-6041.
(2) Letter indicates Lela Lederman is President of Limax (Bayonne) (201) 858-8633.
(3) Documents contain sales invoices from Ayerst International to Ayerst Laboratories (Philippines), but no related drugs on this FDA sample entry.
(4) FDA computer records only list Tolinase. FDA computer records indicate Chloroptic on FDA Sample # 574616.

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FDA SAMPLE #: 574866
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-402550-6
REIMPORTER: Habarx Distributing Corporation
72 Otis Street
West Babylon, New York 11704
REIMPORTATION DATE: 2/14/86
VALUE: $161,353
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Toronto, Canada
STATUS: Released - document review only
MEDICATION: 1650 Symmetrel 100 mg Caps
300 Symmetrel 50 mg/5 ml Syrup
1080 Nubain 10 mg 10's
330 Nubain 20 mg 10's
630 Nubain 10 mg 1's
90 Nubain 20 mg 1's
3000 Coumadin [illegible] mg
600 Coumadin 7.5 mg
450 Coumadin 10 mg
1800 Coumadin 2.5 mg
1650 Coumadin 2 mg
150 Narcan 0.4 mg/ 1 ml Syringe
U.S. MFGR., DATE OF EXPORT: Du Pont, 7/19/85
EXPORTER TO U.S.: Rothwell Enterprizes
161 Abbey Road, London NW6, 7/28/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) K.G. Mohnani, 30 Republic Street, Valletta, Malta, 7/23/85;
(2) International Shipping Group, Miami, Florida (agent for Habarx), 9/28/85;
(3) Habarx Distributing Corporation, Mississauga, Ontario, Canada, 2/10/86.
NOTES: (1) Exporter is Sunil Varma, Rothwell Enterprizes, registered office: Temple House, 20 Holywell Row, London EC2A 4JB.
(2) Letter dated 1/24/86, Varma to FDA Boston, states, "Whilst the goods were lying in Miami, they were being stored in the warehouse of International and Shipping Group. However, we were instructed by the State of Florida to re-export the goods from Miami in view of the fact that the State of Florida insisted on the goods being stored in FDA approved warehouses during

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their transit in Europe. FDA approved warehouses are normally only manufacturing units and are not generally Customs bonded warehouses. We have therefore advised FDA Miami, Mr. Katz, of our intention to export the goods from Miami to Canada but to reimport the same to the USA via Boston. Under our request, FDA Miami have therefore given a rejection on the goods with the knowledge that they will be reimported. Please find attached a certificate from the International and Shipping Group certifying that the goods were in their warehouse during their time in Miami .... We would request you to please therefore treat the information as submitted via this letter as confidential and furthermore due to the confidentiality of business we hope you will be able to clear this consignment without referring with lot no.'s or any other information to E.I. Du Pont de Nemours and Company."

(3) Pharmaceuticals sold to Mohnani for $134,373.87.

(4) New York State Board of Pharmacy issued manufacturer's export certificate.

(5) Letter of credit dated 5/28/85 drawn on Philippine National Bank, Official Depository of the Republic of the Philippines, used to pay for goods from Du Pont by Varma.

(6) B.A.S. Ltd. Cassor and Cooper certificate, P.O. Box 358, Valletta Building dated 9/24/85 states goods imported from U.S. and re-exported to the United Kingdom "has been lying in Malta Customs warehouse during their transit time in Malta."

(7) K.G. Mohnani's stationery is for Kishu's Modern Bride, Specialist of Wedding Accessories, Textiles for Occasions, Gifts and Perfumes."

(8) Malta Customs form dated 7/28/85 lists Varma as the beneficial owner.

(9) Goods apparently warehoused by LEP International in Canada.

(10) Miami FDA Sample # No. 778001.

(11) Handwritten note of telephone conversation says, "Checked with Marty. He is aware of the situation Fl. wants to seize." Marty is apparently Martin Katz of the Orlando District Office.

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FDA SAMPLE #: 574926
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-371277-1
REIMPORTER: Trevor F. Maingot
REIMPORTATION DATE: 2/22/86
VALUE: $12,403
UNLOADING PORT: Miami, Florida
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: St. Lucia, British West Indies
STATUS: Released - document review only
MEDICATION: 1 carton containing Corgard, Corzide, Halog, Mycostatin and Velosef
U.S. MFGR., DATE OF EXPORT: Squibb, 11/7/85
EXPORTER TO U.S.: Renwick and Company, Ltd.
19 Bridge Street, Castries, St. Lucia
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Entry says 2 cartons.
(2) Declared value for Customs on shipping documents is $13,311.
(3) Unloading in Miami, entry (in bond?) to Boston.
(4) Location of lot listed as "Horizon Air."
(5) 4/24/86 from Squibb to FDA supplies invoice, order, packing order, export declaration, letter of instructions and air waybill for sale to Renwick - at a total price of $12,870.
(6) Squibb (4/14/86): "All products were shipped as export goods" except Velosef. According to Squibb (U.S.), Squibb (Puerto Rico) supplied documents showing export.

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FDA SAMPLE #: 574995
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-402696-1
REIMPORTER: Habarx Distributing Corporation
72 Otis Avenue
West Babylon, New York 11704
REIMPORTATION DATE: 3/5/86
VALUE: $52,945 - see notes
UNLOADING PORT: Buffalo, New York
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Toronto, Canada
STATUS: Detained - document review only
MEDICATION: (1) Squibb:
71 units Mycostatin Nystatin Cream 15 grams;
143 units Mycostatin Nystatin Ointment 15 grams;
23 units Kenalog in Orabase Dental Paste 0.1%;
216 bottles (100 Tabs) Corgard (Nadolol Tabs) 80 mg;
15 bottles (1,000 Tabs) Corgard (Nadolol Tabs) 80 mg.
(2) Johnson and Johnson (Ortho):
12 cases Retin-A Cream 0.05% 20 grams;
50 cases Sultrin Triple Sulfa Cream 2.75 oz.;
30 cases Aci-Jel Therapeutic Vaginal Jelly 3 oz.;
25 cases Protostat (Metronidazole) 500 mg. (50 Tabs);
19 cases Protostat (Metronidazole) 250 mg. (100 Tabs).
(3) Schering:
33 cases plus 24 loose packages Garamycin Cream 0.1%;
20 cases Valisone Cream USP 0.1% 15 grams;
13 cases plus 36 loose units Valisone Ointment 0.1% 45 grams, 1.2 mg;
13 cases plus 36 loose units Valisone Cream 0.1% 45 grams;
49 cases Tinactin Antifungal Cream 1% 15 grams;
24 cases Afrin Nose Drops 2/3 fluid ounce 0.05%.
(4) Wyeth:
11 packages Ovrette Tabs (Norgestrel) 0.075 mg.
(5) Marion Laboratories:
4 cases Cardizem 60 mg.;
5 cases Cardizem 30 mg.;
4 cases Pavabid Plateau Caps 150 mg.;
5 cases Carafate 1 gram Tabs;
4 cases (100 Caps) Nitro-Bid 2.5 mg.;
6 cases (60 Caps) Nitro-Bid 2.5 mg.
(6) Johnson and Johnson (McNeil):
4 cases Tolectin 200 mg.;

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2 cases Tolectin 400 mg.;
4 cases Parafon Forte 100 Tabs.
U.S. MFGR., DATE OF EXPORT: See above, dates unknown
EXPORTER TO U.S.: Carimed, Ltd.
c/o Millers Pharmacy, P.O. Box 48,
Grand Cayman, British West Indies
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Six shipments were refused entry by FDA Orlando apparently at the importer's request on 2/5/86. FDA Sample # 778001 (Orlando) is apparently covered by FDA Sample # 574866 (Boston). FDA Sample # 778165 (Orlando) apparently entered Boston after 3/31/86 and was assigned FDA Sample # 599008 (Boston) although 5/21/86 letter from Habarx attorney ascribes that shipment to this sample number. The 5/21/86 letter also indicates that Orlando FDA Sample #'s 778319, 778241, 778484 and 778488 were consolidated upon arrival in Boston under this sample number. That letter also ascribes FDA Sample # 594845 to this entry. That number was not listed on the FDA computer as of 3/31/86. This may be FDA Sample # 778003 also refused entry in Miami.
(2) Document sample only despite expiration dates as early as 9/86.
(3) Habarx Distributing Corporation, Burton Zweigenhaft, also listed at P.O. Box 14308, 91-B Cabot Court, Hauppauge, New York 11788.
(4) As presented to FDA Boston, the old FDA Sample #'s traveled as follows: (a) FDA Sample # 778319, entry value $27,789, Cilag Caribbean (Johnson & Johnson subsidiary) to Hector Henriquez B. Inc., Caracas Baaiweg 36, Willemstaad, Curacao, 10/18/85; (b) FDA Sample # 778241, entry value $19,379, Marion Laboratories to Miller's Pharmacy, Grand Cayman, 9/25/85, to Ben Ramos, International Shipping Group, Miami, undated; (c) FDA Sample # 594845, entry value $21,914, Schering del Caribe to Collins, Ltd., 28 Broad Street, Bridgetown, Barbados, 8/8/85; Collins to Habarx c/o International Shipping, Miami, 9/27/85; (d) FDA Sample # 788484, entry value $52,945, Cilag Caribbean (Johnson & Johnson) to Miller's Pharmacy, Grand Cayman, undated; Carimed, Ltd., c/o Miller's Pharmacy to International Shipping Group, 9/13/85; (e) FDA Sample # 788488, entry value $13,945, Squibb

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(Puerto Rico) to T. Geddes Grant, Ltd., P.O. Box 238, Bridgetown, Barbados, 7/1/85, 8/2/85, 8/20/85, and Wyeth International to T. Geddes Grant ("For: Dispensary Physician") 3/5/85, then to Medimpex, Kingston, Jamaica, 9/3/85 to International Shipping Group, Miami, Florida, 9/10/85.

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FDA SAMPLE #: 581946
FDA DISTRICT: San Francisco, California
CUSTOMS ENTRY #: Unknown
REIMPORTER: MC International
742 Market Street
San Francisco, California 94102
REIMPORTATION DATE: Unknown
VALUE: Unknown
UNLOADING PORT: Unknown
ENTRY PORT: Unknown
EXPORT PORT: Hong Kong
STATUS: Detained - physical sample taken
MEDICATION: Preparation H Suppositories
Dristan Tabs
U.S. MFGR., DATE OF EXPORT: Whitehall Laboratories
EXPORTER TO U.S.: MC International
GPO Box 10265, Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: FDA mail collection report
(10/24/85) only document provided

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FDA SAMPLE #: 598574
FDA DISTRICT: Boston, Massachusetts
CUSTOMS ENTRY #: 86-372430-3
REIMPORTER: Trevor F. Maingot
REIMPORTATION DATE: 3/20/86
VALUE: $42,591
UNLOADING PORT: Boston, Massachusetts
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: St. John's, Antigua
STATUS: Released - document review only
MEDICATION: 576 Vibramycin Caps 100 mg 50's
300 Vibramycin Tabs 100 mg 50's
U.S. MFGR., DATE OF EXPORT: Pfizer, 3/7/86
EXPORTER TO U.S.: Hutchinson (Antigua) Ltd.
P.O. Box 1048, St. John's, Antigua
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Not on FDA computer list as of 3/31/86.
(2) Notes of FDA telephone confirmation with Pfizer indicates that at least 576 bottles were to be shipped from Hutchinson to St. Kits Hospital, Antigua.
(3) 4/8/86 FDA tells Customs it is okay to permit goods to be moved to non-bonded warehouse in broker's custody.
(4) Pfizer invoice to Hutchinson is for $40,471.

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FDA SAMPLE #: 642782
FDA DISTRICT: San Francisco, California
CUSTOMS ENTRY #: 85-359610-7
REIMPORTER: Abdor, Inc.
86-95 Sancho Street
Holliswood, New York 11423
REIMPORTATION DATE: 9/9/85
VALUE: $30,920
UNLOADING PORT: San Francisco, California
ENTRY PORT: San Francisco, California
EXPORT PORT: Hong Kong
STATUS: Detained - physical sample only
MEDICATION: 3500 bottles 5 mg Ditropan 100's
95 bottles 5 mg Ditropan 1000's
30 bottles 4 mg Medrol 100's
50 bottles 100 mg Macrodantin 100's
95 bottles Enduronyl 100's
105 bottles 5 mg Enduron 100's
U.S. MFGR., DATE OF EXPORT:
Marion Laboratories - Ditropan;
Abbott - Enduronyl and Enduron;
Upjohn - Medrol;
Norwich-Eaton - Macrodantin
EXPORTER TO U.S.: Man hing Dispensary
213 Queen's Road Central, Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) See FDA Sample # 642818 re: Abdor.
(2) No documents of sale to Man hing.

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FDA SAMPLE #: 642790
FDA DISTRICT: San Francisco, California
CUSTOMS ENTRY #: 85-444162-4
REIMPORTER: Victor Sales Company
c/o MC International
742 Market Street
San Francisco, California 94102
REIMPORTATION DATE: 9/8/85
VALUE: $55,703
UNLOADING PORT: San Francisco, California
ENTRY PORT: San Francisco, California
EXPORT PORT: Guam
STATUS: Detained - document reivew only
MEDICATION: Tegopen Caps 500 mg 100's
Tegopen Caps 250 mg 100's
Salutensin 100's
Salutensin 1000's
Vasodilan 1000's
Peri-Colace 1000's
Peri-Colace 250's
U.S. MFGR., DATE OF EXPORT:
Bristol-Myers - Tegopen, Salutensin;
Mead Johnson - Vasodilan, Peri-Colace
EXPORTER TO U.S.: Westpac Medical Supply
P.O. Box 6265, Tamunino, Guam
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: FDA notice and sampling documents only
provided -- no commercial documents.

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FDA SAMPLE #: 642818
FDA DISTRICT: San Francisco, California
CUSTOMS ENTRY #: 85-359696-5
REIMPORTER: Abdor, Inc.
86-95 Sancho Street
Holliswood, New York 11423
REIMPORTATION DATE: 9/27/85
VALUE: $92,537
UNLOADING PORT: Miami, Florida
ENTRY PORT: San Francisco, California
EXPORT PORT: Belize City, Belize
STATUS: Detained -- physical sample taken
MEDICATION: 750 Cleocin Caps 150 mg 100's
500 Tolinase 250 mg 100's
2750 Tolinase 250 mg 200's
500 Provera 10 mg 100's
300 Medrol 4 mg 100's
U.S. MFGR., DATE OF EXPORT: Upjohn, 7/16/85
EXPORTER TO U.S.: Commodity Trading Company
P.O. Box 619, Belize City, Belize, 9/9/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Farm-I-Ceuticals, Ltd., 13 Cleghorn Street, Belize City, Belize
NOTES: (1) Abdor has been source of goods for IDE.
(2) Upjohn invoice was for $84,999.
(3) Airway bill from Trevor Roberts c/o Billy Valdez, Belize City to Matton Company, 244 Jackson Street, San Francisco.
(4) Commodity Trading Company (T.M. Roberts) invoiced (9/9/85) Farm-I-Ceuticals for shipping costs to California and Abdor for goods (9/2/85). No documents transferring title from Farm-I-Ceuticals to Commodity Trading Company.
(5) Commodity Trading Company letterhead says, "Building Materials, Pharmaceuticals, Dry Goods, Agriculture."

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FDA SAMPLE #: 642821
FDA DISTRICT: San Francisco, California
CUSTOMS ENTRY #: 85-440341-3
REIMPORTER: Veterinary Services Inc.
416 North Jefferson Avenue
Modesto, California 95351
REIMPORTATION DATE: 8/27/85
VALUE: $17,825
UNLOADING PORT: San Francisco, California
ENTRY PORT: San Francisco, California
EXPORT PORT: Toronto, Canada
STATUS: Detained - physical sample analyzed
MEDICATION: 8 drums Penicillin G. Potassium
7 drums Streptomycin Sulfate Base
U.S. MFGR., DATE OF EXPORT: See notes
EXPORTER TO U.S.: Gentex Pharmaceuticals
2133 Royal Windsor Drive, Building 31, Mississauga,
Ontario, Canada L5J 1K5
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Laboratory document supplied
reflects superficial analysis.
(2) FDA Computer says Eli Lilly is the manufacturer --
no Eli Lilly documents.

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FDA SAMPLE #: 642824
FDA DISTRICT: San Francisco, California
CUSTOMS ENTRY #: 85-444342-8
REIMPORTER: MC International
742 Market Street
San Francisco, California 94102
REIMPORTATION DATE: 9/2/85
VALUE: $1788
UNLOADING PORT: Oakland, California
ENTRY PORT: Oakland, California
EXPORT PORT: Hong Kong
STATUS: Detained - document review only
MEDICATION: 54.5 dozen Preparation H Ointment
50 dozen Anacin Tabs (50's and 100's)
2 dozen Dristan Tabs (24's)
U.S. MFGR., DATE OF EXPORT: Whitehall,
date not available
EXPORTER TO U.S.: MC International
Room 2B Man Lock Comm Building, 89-93 Bohan Strande,
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Detained on importer's presmises.
(2) Over-the-counter goods.
(3) MC International (San Francisco) either is also
known as Victor Sales Company or is agent for Victor
Sales Company.

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FDA SAMPLE #: 642885
FDA DISTRICT: San Francisco, California
CUSTOMS ENTRY #: 86-339641-4
REIMPORTER: Alza Corporation
1454 Faber Place
Palo Alto, California 94304
REIMPORTATION DATE: 10/18/85
VALUE: $32,240
UNLOADING PORT: San Francisco, California
ENTRY PORT: San Francisco, California
EXPORT PORT: Mississauga, Ontario, Canada
STATUS: Detained - physical sample taken
MEDICATION: 124,000 patches Transderm-N TTS
5 Coramine
U.S. MFGR., DATE OF EXPORT: Unspecified,
presumably CIBA-GEIGY
EXPORTER TO U.S.: CIBA-GEIGY Canada, Ltd.
6860 Century Avenue, Mississauga, Ontario, Canada, L5N
2W5
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: CIBA invoice says, "Protect from
extreme heat and cold." Shipped by truck.

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FDA SAMPLE #: 646471
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 85-140218-7
REIMPORTER: Flavine International, Inc.
231 Herbert Avenue
Closter, New Jersey
REIMPORTATION DATE: 9/9/85
VALUE: $28,250
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Hamburg, West Germany
STATUS: Detained - document review only
MEDICATION: 5 Kgs. (net) Hydrocortisone
Base Micronized USP
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: APC Trading GmbH
Papenstrasse 32, D-2000 Hamburg 76, West Germany
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) PDR lists Organon as
manufacturer, but FDA computer print out says,
"analytical results" indicates Upjohn is manufacturer;
(2) See Note 1 on FDA Sample # 790502

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FDA SAMPLE #: 646797
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 85-578481-2
REIMPORTER: MWM Chemical Corporation
270 Madison Avenue
New York, New York 10016
REIMPORTATION DATE: 9/16/85
VALUE: $28,750
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Hamburg, West Germany
STATUS: Refused - document request only
MEDICATION: 50 Kgs. (net) Hydrocortisone Base Micro USP
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: APC Trading Company GmbH
Papenstrasse 32, D-2000 Hamburg 76, West Germany
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) See FDA Sample # 790502 and 646797 - three virtually identical paper trails, one released, one detained, one refused (?)
(2) 50 Kgs quantity on this invoice with value of $28,750. Other two invoices with 5 Kgs quantity have values of $17,700 and $28,250.

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FDA SAMPLE #: 656184
FDA DISTRICT: Dallas, Texas
CUSTOMS ENTRY #: 85-634038-3
REIMPORTER: Third World Fund
3600 McIntosh Road
Port Everglades, Florida 33316
REIMPORTATION DATE: 9/25/85
VALUE: $17,200
UNLOADING PORT: Miami, Florida
ENTRY PORT: Houston, Texas
EXPORT PORT: Belize City, Belize
STATUS: Detained - document request only
MEDICATION: 36 cartons 535 lbs. unspecified "birth control pills"
U.S. MFGR., DATE OF EXPORT: Parke-Davis, date not available
EXPORTER TO U.S.: TWF Relief Station
Fort Street, Georgetown, Grand Cayman. See notes.
OTHER FOREIGN HANDLERS, RECEIPT DATES: See notes
NOTES: (1) Shipped from the U.S. on M.V. "Hybur Intrepid ... now being returned to the United States" (9/16/85).
(2) 1 carton received damage in Belize but no physical inspection by FDA upon return.
(3) Markel International, P.O. Box 22520, Fort Lauderdale, Florida, listed as shipper on some documents.
(4) Hobart International listed as consignee on some documents.

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FDA SAMPLE #: 660047
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-722044-7
REIMPORTER: MWM Chemical Corporation
270 Madison Avenue
New York, New York 10016
REIMPORTATION DATE: 2/6/86
VALUE: $28,750
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: New York, New York
EXPORT PORT: Hamburg, West Germany
STATUS: Detained - physical sample taken
but not analyzed
MEDICATION: Hydrocortisone UPS Micro
U.S. MFGR., DATE OF EXPORT: Upjohn,
date not available
EXPORTER TO U.S.: APC Trading GmbH
Papenstrasse 32, D-2000 Hamburg 76, West Germany,
2/3/86
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) "Delivered to importer's premises."
(2) "APC" stands for "Additives, Pharmaceuticals,
Chemicals."

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FDA SAMPLE #: 660785-90
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-422586-9
REIMPORTER: Giant Merchandising
1529 60th Street
Brooklyn, New York 11219
REIMPORTATION DATE: 9/20/85
VALUE: $96,671
UNLOADING PORT: New York, New York
ENTRY PORT: New York, New York
EXPORT PORT: Rotterdam, Holland
STATUS: Coumadin refused entry,
Triaminic detained - document review only
MEDICATION: 824 pieces Coumadin
504 dozen Triaminic Tabs
608 dozen Triaminicol Tabs 24's
1846 Gelave Shampoo
1021 EFA Shampoo
151 Phinale Detangler
268 Nutri Body
U.S. MFGR., DATE OF EXPORT: Du Pont - Coumadin
Dorsey Laboratories- Triaminic, Triaminicol
EXPORTER TO U.S.: Cubro Trading Company, Ltd.
Ashbourne House, Alberon Gardens, London NW11 OBS,
9/19/85
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) FDA Sample #'s 660785-88 cover
Coumadin ($14,822); 660789-90 cover Triaminic and
Triaminicol ($18,604). Balance of entry includes
Gelave Shampoo, EFA Shampoo, Phinale Detangler and
Nutri Body.
(2) Shipped to U.S. by ocean freight.

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FDA SAMPLE #: 660794
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-159574-1
REIMPORTER: B.H.S. International
589 8th Avenue
New York, New York 10018
REIMPORTATION DATE: 1/19/86
VALUE: $2604
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Hong Kong
STATUS: Refused - physical sample taken but not analyzed
MEDICATION: 18,600 tablets Quibron 300 mg
U.S. MFGR., DATE OF EXPORT: Mead Johnson, date not available
EXPORTER TO U.S.: Sampson Industrial Corporation
General Post Office Box 1107, Hong KOng
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Imported with brass items (products of Hong Kong).
(2) Shipped on the "President Eisenhower," thus, probably not physically entered at JFK.

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FDA SAMPLE #: 660795
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-127118-8
REIMPORTER: Inter-Pharm Export, Inc.
41 Bancker Street
Englewood, New Jersey 07631
REIMPORTATION DATE: 1/2/86
VALUE: $10,624
UNLOADING PORT: New York, New York
ENTRY PORT: New York, New York
EXPORT PORT: Singapore
STATUS: Refused entry - physical sample taken but not analyzed
MEDICATION: 7200 units Preparation H
U.S. MFGR., DATE OF EXPORT: Whitehall, date not available
EXPORTER TO U.S.: Europa Express PTE, Ltd.
#02-05 Afro-Asia Building, 63 Robinson Road, Singapore
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Over-the-counter goods.
(2) Reimported by ocean freight.

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FDA SAMPLE #: 660848-51
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-855505-6
REIMPORTER: Bellarno International, Ltd.
1140 Avenue of the Americas
New York, New York 10036
REIMPORTATION DATE: 12/27/85
VALUE: $47,382
UNLOADING PORT: New York, New York
ENTRY PORT: New York, New York
EXPORT PORT: Singapore
STATUS: Released - physical sample taken
but not analyzed
MEDICATION: 115 bottles Macrodantin Caps
50 mg (500's);
115 bottles Macrodantin Caps 100 mg (1000's)
395 bottles Dantrium Caps 25 mg (100's)
U.S. MFGR., DATE OF EXPORT: Norwich Eaton,
date unknown
EXPORTER TO U.S.: C. Parsram and Company
Suite 403 High Street Plaza, 77 High Street, Singapore
0617
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Port of loading listed as Greece -
Greek ports listed on shipping document.
(2) No documents for export to Singapore or Greece.
(3) Same shipment contains FDA Sample #'s 660848,
660849, 660850 and 660851 (samples taken from
different cartons).
(4) Documents far from complete - no laboratory
analysis.

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FDA SAMPLE #: 660879-81
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-422961-6
REIMPORTER: Glenlow Trading Corporation
565 Fifth Avenue, Suite 715
New York, New York 10017
REIMPORTATION DATE: 10/29/85
VALUE: $108,398
UNLOADING PORT: New York, New York
ENTRY PORT: New York, New York
EXPORT PORT: Rotterdam, Holland
STATUS: Released - document review only
MEDICATION: 544 dozen Lanacort Cream 1/2 oz
328 dozen Vagisil 1 oz
900 Lanacane Cream 1 oz
U.S. MFGR., DATE OF EXPORT: Combe
EXPORTER TO U.S.: Cubro Trading Company, Ltd.
Ashbourne House, Alberon Gardens, London NW11 OBS
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) FDA Sample # 660789 for Lanacort Cream, 660880 for Vagisil and 660881 for Lanacane Cream, invoice also includes 1296 dozen Playtex Tampons, 972 dozen Gelave Instant Conditioner 8 oz., 568 dozen Johnson and Johnson Odor Eaters, 208 dozen Johnson Foot Soap Large, and 522 dozen Johnson Foot Soap Medium, unsampled.
(2) Only documents are FDA Form 701 and Cubro invoice.
(3) Shipped to U.S. by ocean.

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FDA SAMPLE #: 660883
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-171121-1
REIMPORTER: RAK International Inc.
1140 Broadway, Suite 802
New York, New York 10001
REIMPORTATION DATE: 10/31/85
VALUE: $18,000
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: New York, New York
EXPORT PORT: Singapore
STATUS: Refused - document review only
MEDICATION: 24,600 Crest toothpaste
U.S. MFGR., DATE OF EXPORT: Procter and Gamble
EXPORTER TO U.S.: Bajaj Enterprises
#06-05, Song Lin Building, 1 Syed Alwi Road,
Singapore, 0820
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: Toothpaste (refused) part of larger entry ($89,071) including Duracell Batteries, "colour film," and "blank audio cassette tapes TDK D60" with a notation, "We certify that the above goods are made in Belgium/Australia, USA, and Japan."

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FDA SAMPLE #: 660885-87
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-710701-0
REIMPORTER: Masel Supply Company
128 32nd Street
Brooklyn, New York
REIMPORTATION DATE: 1/15/86
VALUE: $344,105
UNLOADING PORT: Newark, New Jersey
ENTRY PORT: Newark, New Jersey
EXPORT PORT: Rotterdam, Holland
STATUS: Detained - physical samples taken
MEDICATION: 964,800 capsules Nitro-Bid 2.5 mg
964,800 capsules Nitro-Bid 6.5 mg
100,800 capsules Ditropan 5 mg
U.S. MFGR., DATE OF EXPORT: Marion Laboratories, date not available
EXPORTER TO U.S.: AVCB, Amsterdam, Netherlands
OTHER FOREIGN HANDLERS, RECEIPT DATES: See notes
NOTES: (1) All products have "DOD [Department of Defense] #" on them.
(2) 1 bottle (100 caps) of each without FDA markings.
(3) Invoice dated 1/3/86 from Fabric Limited, 8 Brentmead Place, London NW11 (Telephone 01-458-1141) to Thrifty Cosmetics, Inc., 6084 15th Avenue, Brooklyn, New York, 11219.
(4) AVCB certification letter says, "Since their arrival from Budapest, been stored in our transit warehouse under good conditions..." (emphasis added).
(5) Ocean freight to the United States.

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FDA SAMPLE #: 660888
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-223689-2
REIMPORTER: Quality King Distributors, Inc.
1095 Long Island Avenue
Deer Park, New York 11729
REIMPORTATION DATE: 1/11/86
VALUE: $97,874
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Hong Kong
STATUS: Released
MEDICATION: 148,176 units (4116 cartons)
Colgate toothpaste
U.S. MFGR., DATE OF EXPORT: Colgate, date unknown
EXPORTER TO U.S.: Galaxy International
6-G, 3-5 Minden Row, Kowloon, Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Release notice (3/19/86) says "Chain of custody established and lot was validated by U.S. manufacturer," but no papers supplied.
(2) Shipped by sea from Hong Kong, but entry filed at JFK Airport.

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FDA SAMPLE #: 660889
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-223713-4
REIMPORTER: Quality King Distributors, Inc.
1095 Long Island Avenue
Deer Park, New York 11729
REIMPORTATION DATE: 1/11/86
VALUE: $125,288
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Hong Kong
STATUS: Released
MEDICATION: 5292 cartons Colgate toothpaste
U.S. MFGR., DATE OF EXPORT: Colgate, date unknown
EXPORTER TO U.S.: Galaxy International
6-G, 3-5 Minden Row, Kowloon, Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: See FDA Sample # 660888

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FDA SAMPLE #: 660988-90
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-126587-7
REIMPORTER: H.B.F. Products, Inc.
41 Bancker Street
Englewood, New Jersey 07631
REIMPORTATION DATE: 11/21/85
VALUE: $12,233
UNLOADING PORT: New York, New York
ENTRY PORT: New York, New York
EXPORT PORT: Singapore
STATUS: 660989-90 unknown;
660988 refused entry - document review only
MEDICATION: 50 dozen Dristan Nasal Mist 15 ml
300 dozen Preparation H Ointment 1 oz
175 dozen Preparation H Ointment 2 oz
U.S. MFGR., DATE OF EXPORT: Whitehall
EXPORTER TO U.S.: C. Parsram and Company
Suite 403 High Street Plaza, 77 High Street, Singapore
0617, 10/26/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: Reimported by ocean freight.

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FDA SAMPLE #: 704310
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-776186-7
REIMPORTER: Empire Sales
4514 11th Avenue
Brooklyn, New York 11219
REIMPORTATION DATE: 2/20/86
VALUE: $349,544
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Brussels, Belgium
STATUS: Detained - document review only
MEDICATION: 242 cartons Anusol-HC Suppositories
U.S. MFGR., DATE OF EXPORT: Parke-Davis, 1/30/86
EXPORTER TO U.S.: Fabric, Ltd.
8 Brentmead Place, London, NW11
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Warner-Lambert (Hong Kong), Ltd.
C and I Building, 88 Hing Fat Street,
Causeway Bay, Hong Kong, 1/30/86
NOTES: (1) Entry says 242 cartons, but
other documents say 1260 cartons.
(2) Companion entry (FDA Sample # 704311) documents
not supplied.

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FDA SAMPLE #: 720417
FDA DISTRICT: San Juan, Puerto Rico
CUSTOMS ENTRY #: 86-630198-5
REIMPORTER: Arguelles Distributors
205 Cruz Street, P.O. Box 1662
San Juan, Puerto Rico 00903
REIMPORTATION DATE: 1/15/86
VALUE: $24,218
UNLOADING PORT: San Juan, Puerto Rico
ENTRY PORT: San Juan, Puerto Rico
EXPORT PORT: Santo Domingo, Dominican Republic
STATUS: Detained - document review only
MEDICATION: 386 Aristocort A Crema
264 Minocin Capulas
36 Minocin 100x100 Tira
U.S. MFGR., DATE OF EXPORT: Lederle,
date not available
EXPORTER TO U.S.: Brugal Co. C par A
No. 57 Avenida John F. Kennedy, Santo Domingo,
Dominican Republic, 1/15/86
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) FDA computer lists consignee as
Masel Supply Company, Brooklyn, New York, and
incorrectly lists Marion Laboratories as manufacturer.
(2) Transported in the baggage of Pura Rodriguez.
Declaration signed by Fermin R. Morales, Inc. for
Arguelles.

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FDA SAMPLE #: 722713
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-139066-1
REIMPORTER: George J. Syage Company
Global Air Cargo
167-10 South Conduit Avenue
Jamaica, New York 11434
REIMPORTATION DATE: 3/8/86
VALUE: $4,292
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Dhaka, Bangladesh
STATUS: Detained - document review only
MEDICATION: 200,000 Penicillin V Potassium USP
U.S. MFGR., DATE OF EXPORT: Bristol-Myers Company, 7/18/85
EXPORTER TO U.S.: Grand Corporation
Dhaka, Bangladesh
OTHER FOREIGN HANDLERS, RECEIPT DATES: Indo-Bangla Pharmaceutical Works, College Road, Barisal, 7/18/85
NOTES: (1) Document sample only despite nine months in Bangladesh.
(2) "Diversion contrary to U.S. law prohibited."

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FDA SAMPLE #: 750510-16
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: Informal
REIMPORTER: Bellarno International, Ltd.
1140 Avenue of the Americas
New York, New York 10036
REIMPORTATION DATE: 9/24/85
VALUE: $40
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Singapore
STATUS: Refused entry - document sample only
MEDICATION: 5 bottles Macrodantin Caps 100 mg 1000's
5 bottles Macrodantin Caps 50 mg 500's
5 bottles Dantrium Caps 25 mg 100's
5 bottles Cogentin Tabs 2 mg 100's
1 bottle Aldomet Injection 250 mg 5 ml
1 bottle Nicobid Tabs 500 mg 100's
5 bottles Urecholine Tabs 10 mg 100's
1 bottle E-Mycin Tabs 250 mg (empty bottle)
1 bottle 40 ml empty vial
1 bottle Oncovin
U.S. MFGR., DATE OF EXPORT:
Norwich Eaton - Macrodantin, Dantrium;
Merck - Cogentin, Aldomet, Urecholine;
USV - Nicobid;
Upjohn - E-Mycin
Lilly - Oncovin and empty bottles
EXPORTER TO U.S.: C. Parsram and Company
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Pharmaceutical samples.
(2) Three empty bottles included - invoice suggests that contents of Lilly bottles unspecific as to medication.

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FDA SAMPLE #: 760932
FDA DISTRICT: Los Angeles, California
CUSTOMS ENTRY #: 86-444629-5
REIMPORTER: The Kendall Company
505 Otay Valley Road
Chula Vista, California 92011
REIMPORTATION DATE: 12/19/85
VALUE: $3375
UNLOADING PORT: Chula Vista, California
ENTRY PORT: Otay Mesa
EXPORT PORT: Tijuana, Mexico
STATUS: Detained - document request only
MEDICATION: 12,000 pieces plastic packing bags
10,000 Ephedrine 1 ml ampules
U.S. MFGR., DATE OF EXPORT: Invenex Laboratories
Gibco Division, The Dexter Corporation, date not available
EXPORTER TO U.S.: Kenmex S.A.
Calle 9 Sur #125, CD Industrial, Tijuana, Mexico
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: Being held on importer's premises.

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FDA SAMPLE #: 768001
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-245709-5
REIMPORTER: Forest Laboratories
10 Wheelock Avenue
Inwood, New York 11696
REIMPORTATION DATE: 10/21/85
VALUE: $19,905
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: New York, New York
EXPORT PORT: Toronto, Canada
STATUS: Detained - document review only
MEDICATION: 8 drums Nitrogard Tabs 3 mg
U.S. MFGR., DATE OF EXPORT: See notes
EXPORTER TO U.S.: See notes
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: FDA Form 701 lists Syntex, Inc., 2100 Syntex Court, Mississauga, Ontario, as manufacturer/shipper. Likely to be manufacturer only - Form 701 is only document.

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FDA SAMPLE #: 768002
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-238968-4
REIMPORTER: Flavine International, Inc.
231 Herbert Avenue
Closter, New Jersey
REIMPORTATION DATE: 10/22/85
VALUE: $29,000
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Hamburg, West Germany
STATUS: Detained - document sample only
MEDICATION: 5 kg Hydrocortisone Base Micro USP XXX1
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: APC Trading GmbH
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: Invoice and FDA Form 701 only documents provided

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FDA SAMPLE #: 771222-5
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-167041-1
REIMPORTER: Emkay Enterprises, Inc.
49 West 32nd Street
New York, New York
REIMPORTATION DATE: 1/15/86
VALUE: $54,279
UNLOADING PORT: Newark, New Jersey
ENTRY PORT: New York, New York
EXPORT PORT: Dubai, United Arab Emirates
STATUS: Detained
MEDICATION: 6782 dozen Crest toothpaste
U.S. MFGR., DATE OF EXPORT: Procter & Gamble, date not available
EXPORTER TO U.S.: Rajkumar Trading Corporation
P.O. Box 432, Dubai, United Arab Emirates
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Over-the-counter products shipped with 1230 dozen "English made soap."
(2) Shipped to the U.S. by ocean freight.

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FDA SAMPLE #: 778001
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-186157-5
REIMPORTER: International Shipping Group
2050 N.W. 94th Avenue
Miami, Florida 33172
REIMPORTATION DATE: 9/28/85
VALUE: $161,353
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: London, England
STATUS: Refused entry - document review only
MEDICATION: 1650 Coumadin 2 mg Tabs 100's
1800 Coumadin 2.5 mg Tabs 100's
3000 Coumadin 5 mg Tabs 100's
600 Coumadin 7.5 mg Tabs 100's
450 Coumadin 10 mg Tabs 100's
150 Narcan 0.4 mg/1 ml Syringe 10 pack
1080 Nubain 10 mg/1 ml Amps 10 pack
330 Nubain 20 mg/1 ml Amps 10 pack
630 Nubain 10 mg/1 ml vial 1 pack
90 Nubain 20 mg/1 ml vial 1 pack
1650 Symmetrel 100 mg Caps 100's
300 Symmetrel 50 mg/5 ml Syrup pints
U.S. MFGR., DATE OF EXPORT: Du Pont, 7/23/85
EXPORTER TO U.S.: Rothwell Enterprizes, Ltd.
161 Abbey Road, London, NW6
OTHER FOREIGN HANDLERS, RECEIPT DATES: K.G. Mohnani
30 Republic Street, Valletta, Malta
NOTES: (1) Habarx Distributing Corporation
(2) Dupont sold at $134,374.
(3) Shipping document indicates that S. Varma, Kismet, Esterano Str., Msida, Malta shipped to S. Varma at Rothwell International, London.
(4) No document transferring title from Mohnani to Rothwell or Varma.
(5) See FDA Sample #'s 574995 and 574866.

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FDA SAMPLE #: 778003
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-187125-8
REIMPORTER: International Shipping Group
2050 N.W. 94th Avenue
Miami, Florida 33172
REIMPORTATION DATE: 9/27/85
VALUE: $21,456
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Bridgetown, Barbados
STATUS: Refused entry - document review only
MEDICATION: 1440 Valisone Ointment 0.1% 45 gm
1440 Valisone Ointment 0.1% 15 gm
1440 Valisone Cream 0.1% 45 gm
1440 Valisone Cream 0.1% 15 gm
1800 Tinactin Cream 0.1% 15 gm
2400 Garamycin Ointment 0.1% 15 gm
2400 Garamycin Cream 0.1% 15 gm
1440 Afrin Nasal Spray 15 ml
1440 Afrin Nose Drops 20 ml
U.S. MFGR., DATE OF EXPORT: Schering-Plough,
8/8/85
EXPORTER TO U.S.: Collins, Ltd.
28 Broad Street, G.P.O. Box 203, Bridgetown, Barbados
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Invoice from Collins
specifies Habarx International Shipping Group as
importer.
(2) Collins invoice lists various expiration dates
from 10/86 to 6/90 but Schering del Caribe, Inc. lists
"expiration date" as 6/84.
(3) Collins invoice lists value at $21,456; Schering
invoice lists cost to Collins at $21,914.
(4) Basis for rejection not clear from documents.
(5) See FDA Sample # 574995.

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FDA SAMPLE #: 778011
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-210804-3
REIMPORTER: General Perfumes and Cosmetics
2250 N.W. 96th Avenue, Building #3
Miami, Florida 33172
REIMPORTATION DATE: 10/12/85
VALUE: $104,757
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Colon, Panama
STATUS: Detained - document review only
MEDICATION: Aftate, Aspergum, Chooz Gum, Correctol, Duration, Feen-A-Mint, St. Joseph Aspirin, Mexana
U.S. MFGR., DATE OF EXPORT: Schering-Plough, 9/12/85
EXPORTER TO U.S.: Expo-Sur Internacional
Zona Libre De Colon, Panama, 10/9/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Serviventas Internacional, S.A.
P.O. Box 4020 Zona Libre de Colon, Panama, date not available;
(2) Expo-Sur, Colon, Panama, 9/30/85.
NOTES: (1) Shipment to and from Panama by ocean freight.
(2) Over-the-counter medication.
(3) Alternate address for Expo-Sur is Ave Manuel Moriaicoza #6, Panama 5, R.D.P.
(4) Invoice missing, shipping document Plough, International to Serviventas does not detail contents.

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FDA SAMPLE #: 778036
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-195448-9
REIMPORTER: Mi-Scott International
REIMPORTATION DATE: 10/17/85
VALUE: $126
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Belgrade, Yugoslavia
STATUS: Refused - document review only
MEDICATION: 1 bottle Halotestin 5 mg Tabs 100's
1 bottle Halotestin 10 mg Tabs 30's
1 bottle Tolinase 100 mg Tabs 100's
1 bottle Tolinase 250 mg Tabs 100's
1 bottle E-Mycin 250 mg Tabs 100's
1 bottle Deltasone 20 mg Tabs 100's
1 bottle Deltasone 10 mg Tabs 100's
1 bottle Motrin 300 mg Tabs 60's
1 bottle Motrin 600 mg Tabs 100's
1 bottle Motrin 400 mg Tabs 100's
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: Interexport
Kolarceva Street 8, Belgrade, Yugoslavia
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Intexpetrol A.G., Kaertner Rin 17, 1010 Wein, Austria,
Attention: Branko Pejovic, 9/21/85
NOTES: (1) Appears to be a sample of
diverted goods.
(2) Only invoice is Upjohn to Intexpetrol (Austria).

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FDA SAMPLE #: 778046
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-182336-8
REIMPORTER: Gulf Drugs Ltd.
5959 N.W. 37th Avenue
Miami?
REIMPORTATION DATE: 8/19/85
VALUE: $500
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Grand Cayman Island,
British West Indies
STATUS: Refused - document review only
MEDICATION: 1 bottle 100 mg Doxycycline Tabs
U.S. MFGR., DATE OF EXPORT: Listed as Pfizer
EXPORTER TO U.S.: Cayman Island Hospital
Grand Cayman Island
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: 1 microcomputer also entered.

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FDA SAMPLE #: 778047
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-182315-1
REIMPORTER: Rageo Properties, Ltd.
1600 N.W. 21st Avenue
Pembrook Pines, Florida 33026
REIMPORTATION DATE: 7/20/85
VALUE: $20,946
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Grand Cayman Island
STATUS: Detained - document review only
MEDICATION: 300 Tolinase 250 mg 100's
418 Tolinase 250 mg 200's
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: Maberry Corporation, Ltd.
P.O. Box 1035, Grand Cayman Island
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: FDA Form 701 and invoice only document.

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FDA SAMPLE #: 778048
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-187218-9
REIMPORTER: Carib Sales, Inc.
13185 N.W. 47th Avenue
Opa Locka, Florida 33054
REIMPORTATION DATE: 10/12/85
VALUE: $92,829
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Cristobal, Panama
STATUS: Detained - document review only
MEDICATION: 1112 Aspergum
363 Chooz
360 Duration
1807 Feen-A-Mint
1271 Mexana
966 Solarcaine
1088 St. Joseph Asprin
U.S. MFGR., DATE OF EXPORT: Schering-Plough
EXPORTER TO U.S.: Paricharm, S.A.
Apartado 603685, Panama
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Reimported by ocean freight.
(2) FDA Form 701 and invoice are only documents.
(3) Over-the-counter products.

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FDA SAMPLE #: 778062
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-133848-7
REIMPORTER: National Business Enterprises
REIMPORTATION DATE: 10/16/85
VALUE: $6739
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Kingston, Jamaica
STATUS: Released - document review only
MEDICATION: 50 bottles Tolinase 250 ml 200's
200 bottles Cleocin 150 ml 200's
U.S. MFGR., DATE OF EXPORT: Upjohn, 8/26/85
EXPORTER TO U.S.: See notes
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) T. Geddes Grant, 8 Ocean Boulevard, P.O. Box 47, Kingston, Jamaica;
(2) Medimpex West Indies, Ltd., 28 Shannon Drive, Kingston, Jamaica.
NOTES: (1) Commercial documents expunged to remove Jamaican names - FDA Form 701 says Bibest Foods is exporter to U.S.
(2) Upjohn invoice for 100 Tolinase and 1500 Cleocin consignee printed name scratched out and Grant inserted.
(3) Medimpex West Indies, Ltd. appears on some documents.

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FDA SAMPLE #: 778133-5
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-195689-8
REIMPORTER: Mi-Scott International
REIMPORTATION DATE: 10/31/85
VALUE: $73,379
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Curacao
STATUS: Released - document review only
MEDICATION: 1800 dozen Lotrimin Cream 15 gm
4000 dozen Valisone Cream .1% 15 gm
1200 dozen Diprosone 15 gm
1400 Valisone Ointment .1% 15 gm
1200 dozen Diprosone Ointment 15 gm
1200 dozen Diprosone Cream 45 gm
1200 Lotrimin Cream 45 gm
4000 dozen Gyne-Lotrimin Vaginal Tabs
U.S. MFGR., DATE OF EXPORT: Schering-Plough
EXPORTER TO U.S.: Blue and White Commodities
Koningsplein, Willemstad, Curacao
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) FDA Form 701 says 544 cartons
and pallets - value may be low.
(2) Invoice named whited out.
(3) Form 701 and invoice only documents.

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FDA SAMPLE #: 778136-7
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-313169-5
REIMPORTER: Mi-Scott International
4300 SW 73rd Avenue
Miami, Florida 33155
REIMPORTATION DATE: 11/3/85
VALUE: $296,790
UNLOADING PORT: Port Everglades, Florida
ENTRY PORT: Port Everglades, Florida
EXPORT PORT: Amsterdam, Holland
STATUS: Released - document review only
MEDICATION: Grecian Formula, Lady Grecian Formula, Gynecort, Johnson's Foot Soap and Spray, Odor Eaters, Lanacane, Lanacort, and Vagisil.
U.S. MFGR., DATE OF EXPORT: Combe
EXPORTER TO U.S.: INCPAB Eastern Overseas, Ltd.
Schipmolen 7, 1035 CE Amsterdam, Holland
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Health and beauty aids mixed in with over-the-counter products.
(2) INCPAB invoice lists "15% export discount, 25% advertising all, 5% prepayment" discounts.
(3) Letterhead similar to others in format but head office: India, branch offices: Nepal, China, Pakistan, Afghanistan, with address listed in Holland.
(4) Invoice is for $74,026 before discount ($44,829 after), but shipping weights suggest $296,790 figure on FDA Form 701 is probably more accurate.
(5) No documents showing export from U.S. or purchase by INCPAB.

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FDA SAMPLE #: 778165
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-187317-5
REIMPORTER: Habarx Distributing Corporation
REIMPORTATION DATE: 11/6/85
VALUE: $250,137
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: See notes
STATUS: Refused entry - document review only
MEDICATION: 3990 dozen Rufen 600 mg 100's
1204 dozen Rufen 600 mg 500's
3859 dozen Rufen 400 mg 100's
1200 dozen Rufen 400 mg 500's
5064 dozen Ru-Tuss Tabs 100's
1200 dozen Ru-Tuss Tabs 500's
960 dozen Zorprin
U.S. MFGR., DATE OF EXPORT: Boots Pharmaceuticals, 9/30/85
EXPORTER TO U.S.: Geminis Shipping Company, S.A. Apartado Postal No. 6-4175, El Dorado, Panama
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Listom Enterprises, Inc., Edificio #62 Locol #1 APDO 4022, Francefield, Zona Libre de Colon, Panama
NOTES: (1) May have been refused at importer's request to avoid Florida seizure.
(2) Las Minas listed as port of lading. Goods appear to have been shipped by ocean freight from Zona Libre de Colon. Shipped from U.S. by ocean freight.

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FDA SAMPLE #: 778188
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-196014-3
REIMPORTER: Mi-Scott International
Miami, Florida
REIMPORTATION DATE: 11/5/85
VALUE: $85,577
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Amsterdam, Holland
STATUS: Released - document sample only
MEDICATION: 6328 assorted bottles Synthroid
612 assorted bottles Choloxin
U.S. MFGR., DATE OF EXPORT: Flint Pharmaceutical,
date not available
EXPORTER TO U.S.: United Africa, Inc.
Schipmolen 7, 1035 CE Amsterdam, Holland
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Letterhead of United Africa says
main office - Benin, branch offices - Togo, Nigeria.
(2) See FDA Sample # 436439 - importer, certificate
signer (Rajen Pahladsingh) and Amsterdam address of
shipper are identical, but company name and offices
(Caribbean) are different.

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FDA SAMPLE #: 778225
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-217075-4
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 11/13/85
VALUE: $48,003
UNLOADING PORT: Chicago, Illinois
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Detained -- document sample only
MEDICATION: 1440 bottles Tolectin Tabs
1440 bottles Parafon Forte Tabs & see notes
U.S. MFGR., DATE OF EXPORT: Johnson & Johnson, 9/25/85; Marion Laboratories
EXPORTER TO U.S.: Elmcrest Trading, 11/5/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Johnson & Johnson (Hong Kong), Ltd.
2605 Sun Hung Kai Centre, 30 Harbour Road, Hong Kong, 9/25/85;
(2) Chung Ching Dispensary
81 Hak Po Street 6/F, Hong Kong, 10/25/85.
NOTES: (1) Chawla family owns both Elmcrest and Sona.
(2) Alternate address for Sona - 2315 N.W. 107th Avenue S. #20, Miami, Florida 33172.
(3) Entry in Miami, goods unloaded in Chicago.
(4) Documents for Cardizem, Nitro-Bid, Carafate and Pavabid (Marion Laboratories) not supplied.

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FDA SAMPLE #: 778241
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #:
REIMPORTER: Inter[illegible]ional Shipping Group
2050 N.W. 94th Avenue
Miami, Florida 33172
REIMPORTATION DATE: 11/6/85
VALUE: $19,194
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Grand Cayman Island
STATUS: Refused - document request only
MEDICATION: 360 Cardizem 30 mg 100's
288 Cardizem 60 mg 100's
288 Nitro-Bid 2.5 mg 60's
432 Nitro-Bid 2.5 mg 100's
360 Carafate Tabs 100's
144 Pavabid Caps 100's
U.S. MFGR., DATE OF EXPORT: Marion Laboratories, date not available
EXPORTER TO U.S.: Miller's Pharmacy
Grand Cayman
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: See FDA Sample # 574995.

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FDA SAMPLE #: 778263
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-217085-1
REIMPORTER: Sona Distributors
2315 NW 107th Avenue S. #20
Miami, Florida 33172
REIMPORTATION DATE: 11/16/85
VALUE: $95,171
UNLOADING PORT: Chicago, Illinois
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released -- document sample only
MEDICATION: 191 bottles Naldecon Tabs
4000 bottles Medrol Tabs
U.S. MFGR., DATE OF EXPORT:
Naldecon: Bristol-Myers, 7/9/85;
Medrol: Upjohn, 9/26/85.
EXPORTER TO U.S.: Elmcrest Trading, 11/8/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Naldecon: (1) Bristol-Myers (Malaysia) SND. BHD.
Selangor, Malaysia, 7/9/85;
(2) Farmasi Kim
51 Jin SS 2/64, Petoling Joya, Selangor, Malaysia,
date not available;
(3) Satim Pharmacare, Singapore, 9/19/85.
Medrol:
(1) The Getz Corporation
100 F Pasir Panjang Road, Singapore 0511, 9/26/85;
(2) Satim Pharmacare, 11/7/85.
NOTES: (1) Entry in Miami, goods unloaded
in Chicago.
(2) Medrol sold through Upjohn Worldwide, Hong Kong,
but delivered directly to Getz Corporation.
(3) Medrol shipped by ocean freight to Singapore.
(4) See notes 1 and 2 on FDA Sample # 778225.

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FDA SAMPLE #: 778264
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: CF-3311
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 11/21/85
VALUE: $6,326
UNLOADING PORT: Chicago, Illinois
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document sample only
MEDICATION: 760 bottles Aquasol A Caps (100's)
U.S. MFGR., DATE OF EXPORT: Armour Pharmaceutical, 10/22/85
EXPORTER TO U.S.: Elmcrest Trading, 11/14/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Watsons Pharmaceutical Ltd.
5th Floor JDH Centre, Wan Hoi Street
Hung Hom, Kowloon, Hong Kong, 10/22/85;
(2) Chung Ching Dispensary
81 Hak Po Street 6/F, Hong Kong, 11/7/85.
NOTES: (1) Entry in Miami, goods unloaded in Chicago.
(2) See notes 1 and 2 on FDA Sample # 778225.

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FDA SAMPLE #: 778265
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-217096-1
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 11/21/85
VALUE: $10,704
UNLOADING PORT: Chicago, Illinois
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Detained -- document sample only
MEDICATION: 380 bottles Kutrase Caps 100's
932 bottles Levsin Tabs 100's
U.S. MFGR., DATE OF EXPORT: Kremers-Urban, International, 10/6/85
EXPORTER TO U.S.: Elmcrest Trading
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) The New China Drug Company
c/o Cochrane Commercial House, 15 Cochrane Street, 5th Floor, Hong Kong, 10/6/85;
(2) Chung Ching Dispensary, Ltd.
81 Hak Po Street 6/F, Hong Kong, 11/11/85
NOTES: (1) Shipped to Hong Kong by ocean freight from Baltimore.
(2) Entry in Miami, goods unloaded in Chicago.
(3) Ku-Zyme, Calciferol, Kudrox, Nitrol and Urbamin shipped with Kutrase to Hong Kong at price of $17,936.
(4) See notes 1 and 2 for FDA Sample # 778225.

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FDA SAMPLE #: 778318
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-217095-8
REIMPORTER: Sona Distributors
2315 N.W. 107th Avenue S. #20
Miami, Florida 33172
REIMPORTATION DATE: 11/21/85
VALUE: $54,268
UNLOADING PORT: Chicago, Illinois
ENTRY PORT: Boston, Massachusetts
EXPORT PORT: Hong Kong
STATUS: Detained - document sample only
MEDICATION: 1100 bottles Macrodantin Caps 50's
1100 bottles Macrodantin Caps 100's
U.S. MFGR., DATE OF EXPORT: Norwich Eaton,
10/19/85
EXPORTER TO U.S.: Elmcrest Trading, 11/14/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Edward Keller, Ltd.
G.P.O. Box 659, Hong Kong, 10/19/85;
(2) Chung Ching Dispensary, 10/30/85.
NOTES: (1) Entry in Miami, goods unloaded
in Chicago.
(2) Sold to Edward Keller, but for the account of
Chung Ching as per 7/30/85 contract.
(3) Contract between Eaton Laboratories (Puerto Rico)
and Chung Ching only for 1000 bottles of each.
(4) See notes 1 and 2 on FDA Sample # 778225.

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FDA SAMPLE #: 778319
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-159795-6
REIMPORTER: International Shipping Group
REIMPORTATION DATE: 11/16/85
VALUE: $27,789
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Curacao
STATUS: Refused - document sample only
MEDICATION: 192 Retin-A Gel .01%;
360 Persa-Gel 10%
360 Persa-Gel 5%
144 Protostat 250 mg Tabs (100's)
432 Parafon Forte Tabs (100's)
120 Retin-A Cream .05%
360 Sultrin Vaginal Tabs (20's) with applicator
432 Tolectin Tabs (100's)
360 Aci-Jel with applicator
U.S. MFGR., DATE OF EXPORT:
Johnson & Johnson, date not available
EXPORTER TO U.S.: Hector Henriquez B., Inc.
Lafar Antillana Inc., Caracasbaaiweg 38, Curacao
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Invoice says for the account of
Human Capital, Inc., 370 Lexington Avenue, Suite 806,
New York, New York 10017, c/o International Shipping.
(2) See FDA Sample # 574995

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FDA SAMPLE #: 778361
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-400981-0
REIMPORTER: Lund and Pullara, Inc.
4 East Port Road, Suite 401
Riviera Beach, Florida 33404
REIMPORTATION DATE: 11/11/85
VALUE: $133,811
UNLOADING PORT: West Palm Beach, Florida
ENTRY PORT: West Palm Beach, Florida
EXPORT PORT: Las Minas, Panama
STATUS: Detained - document sample only
MEDICATION: 6227 cartons, including toothpaste, mouthwash, toothbrushes, perfume and cologne
U.S. MFGR., DATE OF EXPORT: Lever Brothers Company, Inc., New York, 10/9/85
EXPORTER TO U.S.: Despachadora Andrea, Zona Libre de Colon, Panama, 10/29/85
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Imported "for the account of" Victory International, Lane and Duke Terminal, Jacksonville, Florida 32206.
(2) 6227 cartons "toilet preparations."
(3) Shipped by containerized ocean freight to and from Panama.
(4) Lever Brothers (New York) acted as agent for Unilever Export Limited, Bristol, United Kingdom.

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FDA SAMPLE #: 778374
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192457-4
REIMPORTER: Sona Distributors
REIMPORTATION DATE: 12/17/85
VALUE: $92,443
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Singapore
STATUS: Released - document sample only
MEDICATION: 2000 vials Acthar Lypholized 40
600 bottles Aquasol A Caps
600 tubes Biozyme-C Ointment
2000 bottles Nicobid Temps 500 mg
U.S. MFGR., DATE OF EXPORT:
For Acthar, Aquasol and Biozyme - Armour Pharmaceuticals, 11/1/85;
For Nicobid - USV Pharmaceuticals, date not available.
EXPORTER TO U.S.: Satim Pharmacare
Singapore
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Revlon Health Care S.E.A. Ptd., Ltd.
#12-16 International Plaza, 10 Anson Road,
Singapore 0207, 11/1/85
NOTES: (1) Shipped from Singapore 11/30/85.
(2) No record of Nicobid shipment to Revlon (Singapore).

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FDA SAMPLE #: 778377
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192457-4
REIMPORTER: Rageo Properties, Ltd.
1600 N.W. 21st Avenue
Pembrook Pines, Florida 33026
REIMPORTATION DATE: 11/27/85
VALUE: $19,348
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Cayman Islands
STATUS: Detained - document sample only
MEDICATION: 576 Cardizem Tabs 30 mg
576 Cardizem Tabs 60 mg
U.S. MFGR., DATE OF EXPORT:
Marion Laboratories, 9/25/85
EXPORTER TO U.S.: Miller's Pharmacy
P.O. Box 48, Grand Cayman Island, British West Indies
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) George Shim is name at
Rageo Properties.
(2) Contract (9/25/85) specifies only 200 units of
Cardizem (together with Nitro-Bid, Carafate and
Pavabid).
(3) Shipped to Miami by ocean freight.

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FDA SAMPLE #: 778413
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: Not listed
REIMPORTER: Sona Distributors
Miami, Florida
REIMPORTATION DATE: 11/30/85
VALUE: $3,531
UNLOADING PORT: Chicago, Illinois
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document sample only
MEDICATION: 302 bottles Peri-Colace
Caps (1000's);
768 bottles Naldecon Tabs (500's)
U.S. MFGR., DATE OF EXPORT:
Peri-Colace - Mead Johnson, 6/24/85;
Naldecon - Bristol-Myers, 8/30/85
EXPORTER TO U.S.: Elmcrest Trading Company
Hong Kong, 11/20/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Bristol-Myers (Malaysia), Belanbor, Malaysia, date not available;
(2) Farmasi Kim, Singapore, date not available;
(3) Satim Pharmacare, Singapore, 11/14/85;
(4) Elmcrest Trading, Hong Kong, 11/17/85
NOTES: (1) Entry says value $3531;
invoice (Elmcrest to Sona) for same medicine says $759,149.60 (Hong Kong) or about $97,327 (U.S.);
export license (Hong Kong Government) says $440,634.24 (Hong Kong) or about $56,492 (U.S.).
(2) Bristol-Myers to Bristol-Myers (Malaysia) - 900 bottles by ocean freight.
(3) Bristol-Myers shipped 480 cases of Mead Johnson's Peri-Colace caps (1000's) to Bristol-Myers (Malaysia). No documents of Mead Johnson to Bristol-Myers.
(4) No legible documents, Bristol-Myers (Malaysia) to Formasi Kim.

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FDA SAMPLE #: 778418
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-196919-9
REIMPORTER: Mi-Scott International
REIMPORTATION DATE: 12/26/85
VALUE: $261,169
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Las Minas, Panama
STATUS: Released - document sample only
MEDICATION: Neutrogena Soap, Shampoo, Hand Cream, Body Oil, Rain Bath.
U.S. MFGR., DATE OF EXPORT: Neutrogena
EXPORTER TO U.S.: Ecuatooriana De Exportacion Zona Libre de Colon, Panama
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Health and beauty aides claimed.
(2) FDA computer list says Neutrogena Acne Formula Soap.
(3) Documents incomplete.

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FDA SAMPLE #: 778432
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192464-2
REIMPORTER: Sona Distributors
Miami, Florida
REIMPORTATION DATE: 12/17/85
VALUE: $280,013
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Singapore
STATUS: Released - document review only
MEDICATION: 1860 bottles Deprol Tabs (100's)
732 bottles Soma Compound Tabs (500's)
432 bottles Meprospan Caps 400 mg (100's)
U.S. MFGR., DATE OF EXPORT: Carter-Wallace, 8/16/85
EXPORTER TO U.S.: Satim Pharmacare, Singapore
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Carter-Wallace, 1702 Tung Wah Mansion, 199-203 Hennessy Road, Wanchai, Hong Kong, 9/18/85;
(2) J.L. Morison (Hong Kong), Ltd. Son and Jones (M) SDN. BHD., Morison House, No. 20 Jalan 223/51A, Petaling Jaya, Selangor, Malaysia, 10/31/85;
(3) Satim Pharmacare, 11/29/85
NOTES: (1) Shipped to Hong Kong by ocean freight.
(2) Carter-Wallace (Hong Kong) and J.L. Morison order dates (7/30/85) are identical. Satim order date (7/29/85) shipped to Malaysia by ocean freight.

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FDA SAMPLE #: 778443
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192468-4
REIMPORTER: Sona Distributors
REIMPORTATION DATE: 12/20/85
VALUE: $117,636
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Singapore
STATUS: Detained - document review only
MEDICATION: 1008 bottles Duricef Oral Suspension 250 mg 100 ml;
599 bottles Quibron Caps 1000's
U.S. MFGR., DATE OF EXPORT: Mead Johnson, date not available
EXPORTER TO U.S.: Satim Pharmacare, Singapore
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Bristol-Myers (Malaysia), Selangor, Malaysia, 11/13/85 for Duricef, 11/26/85 for Quibron;
(2) Farmasi Kim, Malaysia, 12/4/85 for Quibron;
(3) Sri Suyan SDN. BHD., 59 Jalan 2/90 Teman Pertame, 3 1/2 mile Cheras, Kuala Lumpur, Malaysia, 11/21/85 for Duricef;
(4) Satim Pharmacare 12/9/85 for Quibron, 11/29/85 for Duricef.
NOTES: (1) No documents Mead Johnson to Bristol-Myers.
(2) Bristol-Myers (Malaysia) documents do not specify quantities clearly.

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FDA SAMPLE #: 778464
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-159990-9
REIMPORTER: Gulf Drug Company
Hialeah, Florida
REIMPORTATION DATE: 12/12/85
VALUE: $1173
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Grand Turk, British West Indies
STATUS: Detained - document review only
MEDICATION: Illegible
U.S. MFGR., DATE OF EXPORT: Various manufacturers, dates not listed
EXPORTER TO U.S.: Illegible
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: Only document is nine-page illegible shopping list.

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FDA SAMPLE #: 778495
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192459-0
REIMPORTER: Sona Distributors
Miami, Florida
REIMPORTATION DATE: 12/10/85
VALUE: $69,930
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Singapore
STATUS: Detained - document sample only
MEDICATION: 7200 bottles "Sensitive Eyes"
Saline Solution 237 ml
9600 bottles Sterile Daily Cleaner 45 ml
4800 bottles Sterile Lens Lubricant 15 ml
U.S. MFGR., DATE OF EXPORT: Bausch and Lomb,
8/23/85
EXPORTER TO U.S.: Satim Pharmacare
Singapore, 11/9/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Bausch and Lomb (Singapore) Ptr. Ltd.
10 Anson Road, Suite 33-10, International Plaza,
Singapore, 8/23/85;
(2) Satim Pharmacare, 11/8/85.
NOTES: (1) Over-the-counter?
(2) Shipped to and from Singapore by ocean freight.

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FDA SAMPLE #: 778511
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 5004116 (CF 3311)
REIMPORTER: Sona Distributors
Miami, Florida
REIMPORTATION DATE: 12/23/85
VALUE: $6789
UNLOADING PORT: New York, New York
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Unknown
MEDICATION: 384 bottles Kutrase Caps (100's)
324 bottles Levsin Tabs 0.125 mg (100's)
U.S. MFGR., DATE OF EXPORT: Kremers-Urban,
9/18/85
EXPORTER TO U.S.: Elmcrest Trading, 12/16/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) The New China Drug Company, Hong Kong, 10/23/85;
(2) Chung Ching Dispensary, Ltd., Hong Kong, 11/29/85;
(3) Elmcrest Trading, Ltd., Hong Kong, 12/10/85.
NOTES: (1) Shipped by ocean freight to
Hong Kong from Philadelphia.
(2) Part of large order by The New China Drug Company,
including Ku-Zyme, Calciferol, Kudrox, Nitrol and
Urbamin.

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FDA SAMPLE #: 778512
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192496-9
REIMPORTER: Sona Distributors
Miami, Florida
REIMPORTATION DATE: 1/10/86
VALUE: $48,407
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Detained - document review only
MEDICATION: Preparation H, Anacin, Dristan, Freezone, Correctol, Deep Strength, Aftate Gel, Duration
U.S. MFGR., DATE OF EXPORT: Whitehall; Plough, dates not available
EXPORTER TO U.S.: Elmcrest Trading
OTHER FOREIGN HANDLERS, RECEIPT DATES: Whitehall:
(1) C. Cordon and Company (Hong Kong) Ltd. Rooms 411-413, No. 9, Ice House Street, Central, Hong Kong, 1/9/85;
(2) Chung Ching Dispensary, Hong Kong, 12/2/85;
(3) Elmcrest Trading, Hong Kong, 12/10/85.
Plough:
(1) Moson International, Ltd.
6 Watson Road, Hong Kong, 9/23/85 and 9/5/85;
(2) Chung Ching Dispensary, Hong Kong, 12/9/85;
(3) Elmcrest Trading, Hong Kong, 12/10/85.
NOTES: (1) Over-the-counter goods.
(2) Whitehall goods part of larger shipment.
(3) Not all Plough goods accounted for at export to Hong Kong.

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FDA SAMPLE #: 778513
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-197076-4
REIMPORTER: Mi-Scott International
Miami, Florida
REIMPORTATION DATE: 12/24/85
VALUE: $280,400
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Curacao
STATUS: Detained - document review only
MEDICATION: Grecian Formula; Gynecort;
Johnson's Foot Soap, Spray and Odor Eaters; Lanacane,
Vagisil.
U.S. MFGR., DATE OF EXPORT: Combe,
date not available
EXPORTER TO U.S.: Unknown
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) 1992 cartons of "toilet preparations."
(2) Invoice of sale dated 12/27/85 (3 days after entry
to U.S.) with seller's name removed.
(3) Invoice for $30,102; declared value $280,400.
(4) Shipper listed as Rice Trading, Konings Plein,
Willemstad, Curacao.
(5) Country of origin listed as France, USA.

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FDA SAMPLE #: 778527
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192495-6
REIMPORTER: Sona Distributors
Miami, Florida
REIMPORTATION DATE: 12/31/85
VALUE: $170,404
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Singapore
STATUS: Detained - document review only
MEDICATION: 4800 bottles Sterile Lens Lubricant
9600 bottles "Sensitive Eyes" Daily Cleaner
7200 bottles "Sensitive Eyes" Saline Solution 237 ml
24,000 bottles "Sensitive Eyes" Saline Solution 355 ml
U.S. MFGR., DATE OF EXPORT: Bausch and Lomb,
10/15/85
EXPORTER TO U.S.: Satim Pharmacare
Singapore, 12/2/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
(1) Bausch and Lomb (Singapore), 10/23/85;
(2) Satim Pharmacare, Singapore, 11/29/85
NOTES: (1) No documents Bausch and Lomb
(Singapore) to intermediary.
(2) Document of sale from intermediary to Satim is
illegible.
(3) Shipped from Singapore by ocean freight.

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FDA SAMPLE #: 778550
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-143434-9
REIMPORTER: Rageo Properties
REIMPORTATION DATE: 1/8/86
VALUE: $13,349
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Solomon, Grand Cayman
STATUS: Detained - document review only
MEDICATION: 240 Tolinase 250 mg (200's)
240 Tolinase 250 mg (100's)
U.S. MFGR., DATE OF EXPORT: Upjohn, 9/26/85
EXPORTER TO U.S.: Miller's Pharmacy
P.O. Box 48, Grand Cayman, British West Indies,
10/7/85
OTHER FOREIGN HANDLERS, RECEIPT DATES: None
NOTES: (1) Detained but on importer's
premises.
(2) Upjohn (Puerto Rico) to Miller's Pharmacy invoice
also contains four bottles Cleocin (100's) and 96
bottles Lincocin (100's).

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FDA SAMPLE #: 778551
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-219557-7
REIMPORTER: Supreme Distributors, Inc.
21121 Telegraph Road
Southfield, Michigan 48034
REIMPORTATION DATE: 1/21/86
VALUE: $22,462
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Colon, Panama
STATUS: Detained - document review only
MEDICATION: Orajel and acne medications
U.S. MFGR., DATE OF EXPORT: Orajel - presume
Commerce Drug
EXPORTER TO U.S.:
Representaciones Del Caribe, S.A.
Zona Libre de Colon, Panama, 1/15/86
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Over-the-counter products.
(2) Imported through Gulf Export, Hialeah, Florida.

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FDA SAMPLE #: 778552
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-403611-5
REIMPORTER: Mi-Scott International
Miami, Florida
REIMPORTATION DATE: 1/22/86
VALUE: $30,343
UNLOADING PORT: West Palm Beach, Florida
ENTRY PORT: West Palm Beach, Florida
EXPORT PORT: Paramaribo, Surinam
STATUS: Detained - document review only
MEDICATION: Anacin, Anbesol, Denorex, Dristan, Freezone, Heet, Outgro, Preparation H, Compound W
U.S. MFGR., DATE OF EXPORT: Whitehall, date not available
EXPORTER TO U.S.: Imsurex
Koningstraat 72, P.O. Box 1360, Paramaribo, Surinam, 1/13/86
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Over-the-counter goods.
(2) Imsurex has offices in Holland - principal is R. Pahladsingh.

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FDA SAMPLE #: 778581
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-217183-4
REIMPORTER: Sona Distributors
Miami, Florida
REIMPORTATION DATE: 1/12/86
VALUE: $201,948
UNLOADING PORT: Seattle, Washington
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Detained - document sample only
MEDICATION: 3500 bottles Meclomen 100's
300 bottles Meclomen 500's
3800 bottles Choledyl 1000's
280 bottles Choledyl 100's
1000 bottles Lopid 100's
768 bottles Kutrase 100's
2784 bottles Levsin 100's
54 bottles Adapin 100's
5 bottles Adapin 1000's
358 bottles Corsym 30 oz.
1194 bottles Allerest 24's
180 bottles Allerest 72's
16 bottles Zaroxolyn 100's
10 bottles Zaroxolyn 500's
U.S. MFGR., DATE OF EXPORT:
Parke-Davis for Meclomen, Choledyl and Lopid;
Kremers-Urban for Kutrase and Levsin;
Penwalt for Adapin and Zaroxolyn;
Pharmacraft for Corsym and Allerest.
(Export dates not listed)
EXPORTER TO U.S.: Elmcrest Trading,
Hong Kong, 1/9/86
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Parke-Davis:
(1) Warner-Lambert (Hong Kong), 5/24/85 - 10/25/85;
(2) Chung Ching Dispensary, Hong Kong, 9/5/85 - 12/24/85;
(3) Elmcrest Trading, Hong Kong, 12/17/85 - 1/7/86.
Kremers-Urban:
(1) The New China Drug Company, c/o Cochrane Commercial House, Hong Kong, 11/4/85;
(2) Chung Ching Dispensary, Hong Kong, 1/6/86;
(3) Elmcrest Trading, Hong Kong, 1/6/86.

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Penwalt and Pharmacraft:
(1) Satim Pharmacare, Singapore, 4/16/85;
(2) M/S Grand Wings International Company, P.O. Box 27196, Singapore, 12/31/85;
(3) Elmcrest Trading, 12/31/85.
NOTES: (1) All shipments to Hong Kong by ocean freight.
(2) Warner-Lambert invoices to its Hong Kong office are dated from 4/26/85 to 10/25/85. Most of the medications returning to the U.S. were parts of larger lots, according to their lot numbers. However, documents showing shipments from the U.S. for lot numbers totaling 2100 bottles of Choledyl were not provided.
(3) Kremers-Urban shipment to The New China Drug Company, Hong Kong, part of larger shipment including Kutapressin, Calciferol, Ku-Zyme, Levsinex and Kudrox, with "free samples" of each.
(4) Penwalt and Pharmacraft both shipped to Singapore by Penwalt Export Division (New York).
(5) The New China Drug Company is "sole agents for Kremers-Urban Company, Milwaukee, Wisconsin, U.S.A."
(6) Penwalt shipment to Satim part of larger order for each medication.

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FDA SAMPLE #: 778665
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-187765-0
REIMPORTER: Orion International, Inc.
1001 N.E. 125th Street, P.O. Box 61-1602
North Miami, Florida 33181
REIMPORTATION DATE: 2/19/86
VALUE: $63,130
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Paramaribo, Surinam
STATUS: Detained - document review only
MEDICATION: 3600 Halog Cream 0.1% 15 gm;
4896 Mycostatin Oral Tabs 100's
U.S. MFGR., DATE OF EXPORT: Squibb,
date not available
EXPORTER TO U.S.: C. Kersten and Company
27 Steenbakkerijstraat, Paramaribo, Surinam
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: Exporter's buying office is in Amsterdam.

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FDA SAMPLE #: 780625-29
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-166873-3
REIMPORTER: Cavalier Sportswear, Inc.
342 River Road
Edgewater, New Jersey 07020
REIMPORTATION DATE: 12/10/85
VALUE: $45,188
UNLOADING PORT: Newark, New Jersey
ENTRY PORT: New York, New York
EXPORT PORT: Dubai, United Arab Emirates
STATUS: Released - physical sample taken but not analyzed
MEDICATION: 112 dozen Crest toothpaste 8.2 oz.
595 dozen Crest toothpaste 6.4 oz.
513 dozen Crest toothpaste 4.6 oz.
612 dozen Crest toothpaste 2.7 oz.
3446 dozen Crest toothpaste 1.4 oz.
U.S. MFGR., DATE OF EXPORT: Procter and Gamble, date unknown
EXPORTER TO U.S.: Rajkumar Trading Corporation
P.O. Box 432, Dubai, United Arab Emirates, 11/11/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: 3464 dozen English made soap (110 grams) and 600 dozen English made soap (142 grams) also contained on invoice.

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FDA SAMPLE #: 780645
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-223726-0
REIMPORTER: Quality King Distributors, Inc.
1095 Long Island Avenue
Deer Park, New York 11729
REIMPORTATION DATE: 2/4/86
VALUE: $99,879
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: JFK Airport, New York
EXPORT PORT: Hong Kong
STATUS: Detained - document review only
MEDICATION: 4199 cartons Colgate toothpaste
U.S. MFGR., DATE OF EXPORT: Colgate, date unknown
EXPORTER TO U.S.: Galaxy International
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: See FDA Sample # 660888, note 2.

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FDA SAMPLE #: 786826-29
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-126587-7
REIMPORTER: H.B.F. Products, Inc.
41 Bancker Street
Englewood, New Jersey 07631
REIMPORTATION DATE: 11/27/85
VALUE: $29,255
UNLOADING PORT: New York, New York
ENTRY PORT: New York, New York
EXPORT PORT: Hong Kong
STATUS: Detained - physical sample taken but not analyzed
MEDICATION: 3600 Bufferin (36's)
3600 Bufferin (60's)
1224 Bufferin (100's)
12,096 Excedrin (36's)
U.S. MFGR., DATE OF EXPORT: Bristol-Myers, date unknown
EXPORTER TO U.S.: Classical Supplies Company, Ltd., G.P.O. Box 6187, Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Shipped from Hong Kong by ocean freight.
(2) Invoice says sold to Mod Garments, Inc., 25 West 37tn Street, New York, New York.
(3) Same shipment contains FDA Sample #'s 786826, 786827, 786828 and 786829 (samples taken from different cartons).

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FDA SAMPLE #: 786830
FDA DISTRICT: New York, New York
CUSTOMS ENTRY #: 86-166873-3
REIMPORTER: Inter-Pharm Export, Inc.
41 Bancker Street
Englewood, New Jersey 07631
REIMPORTATION DATE: 12/26/85
VALUE: $16,945
UNLOADING PORT: New York, New York
ENTRY PORT: New York, New York
EXPORT PORT: Singapore
STATUS: Released - physical sample taken
but not analyzed
MEDICATION: 15,000 Visine Drops 0.5 oz.
U.S. MFGR., DATE OF EXPORT: Leeming Division,
Pfizer, date not available
EXPORTER TO U.S.: S. Mulchand and Sons
(S) Pte., Colombo Court, P.O. Box 8, Singapore 9117
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Same importer address as
H.B.F. Products, FDA Sample #'s 786826-29.
(2) No documents on export from U.S. on transactions
overseas.

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FDA SAMPLE #: 787016
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-405416-9
REIMPORTER: Mi-Scott International
REIMPORTATION DATE: 9/23/85
VALUE: $29,695
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Surinam
STATUS: Detained - document review only
MEDICATION: 208 dozen Anacin Tabs 50's
65 dozen Anacin Tabs 100's
65 dozen Anacin Tabs 200's
78 Anbesol .31 oz
130 dozen Arthritis Pain Formula 40's
65 dozen Arthritis Pain Formula 100's
65 dozen Dristan L.L. Nasal Spray .5 oz
39 dozen Dristan Menthol Nasal Spray .5 oz
130 dozen Advanced Formula Dristan Tabs 24's
65 dozen Advanced Formula Distran Tabs 50's
130 dozen Preparation H Ointment 1 oz
130 dozen Preparation H Ointment 2 oz
130 dozen Preparation H Suppositories 12's
78 dozen Preparation H Suppositories 24's
U.S. MFGR., DATE OF EXPORT: Whitehall Laboratories
EXPORTER TO U.S.: Imsurex
Koningstraat 72, P.O. Box 1360, Paramaribo, Surinam
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Reimported by "ocean tramp."
(2) Over-the-counter products but labeled as health and beauty aids.
(3) Declaration from R. Pahladsingh, Planetenlaan 22 Croningen, Holland that goods were originally exported from "New York on or about August 1985" -- no documents.

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FDA SAMPLE #: 788448
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252625-3
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/9/85
VALUE: $406,249
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 744 bottles Soma Tabs 350 mg 500's
1008 bottles Organidin Tabs 100's
1200 tubes Retin-A Gel 0.025% 15 gm
1200 tubes Retin-A Cream 0.1% 20 gm
1200 tubes Retin-A Gel 0.1% 20 gm
120 tubes Halog Cream 0.1% 60 gm
600 tubes Halog Cream 0.1% 15 gm
5005 vials Aldomet Inj. 250 mg/5 ml
198 boxes Cogentin Inj. 2 mg/2 ml (6 amps)
990 bottles Cogentin Tabs 2 mg 100's
990 bottles Decadron Inj. 4 mg/ml x 5 ml
308 bottles Decadron-LA Suspension 8 mg/ml x 5 ml
1210 bottles ColBENEMID Tabs 100's
308 bottles Urecholine Tabs 10 mg 100's
10,212 bottles Ditropan Tabs 5 mg 100's
702 bottles Ditropan Tabs 5 mg 1000's
125 bottles Pavabid Caps 150 mg 100's
50 bottles Pavabid Caps 150 mg 5000's
U.S. MFGR., DATE OF EXPORT:
Wallace - Soma, Organidin;
Johnson & Johnson - Retin-A;
Squibb - Halog;
Merck - Aldomet, Cogentin, Decadron, ColBENEMID, Urecholine;
Marion Laboratories - Ditropan, Pavabid
EXPORTER TO U.S.: Elmcrest Trading
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: FDA Form 701 and Elmcrest invoice only documents provided.

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FDA SAMPLE #: 788449
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252626-6
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/9/85
VALUE: $48,178
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Detained - document review only
MEDICATION: 1956 Xanax Tabs 0.5 mg 100's
1476 Xanax Tabs 0.25 mg 100's
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: FDA Form 701 and Elmcrest invoice
only documents provided.

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FDA SAMPLE #: 788450
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252627
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/9/85
VALUE: $12,615
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 300 bottles Oxsoralen Caps 10 mg 100's
300 bottles Trisoralen Tabs 5 mg 100's
U.S. MFGR., DATE OF EXPORT: Elder Pharmaceuticals
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) FDA Form 701 and Elmcrest invoice
only documents provided.
(2) "Location of lot" was Sona.

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FDA SAMPLE #: 788458
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-537852-1
REIMPORTER: National Business Enterprises
3300 North 29th Avenue, Suite 103
Hollywood, Florida
REIMPORTATION DATE: 8/11/85
VALUE: $30,720
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Singapore
STATUS: Refused entry - document review only
MEDICATION: 1200 Aldomet Injection 250 mg
1200 Cogentin Tabs 2 mg (100's)
600 Urecholine Tabs 10 mg (100's)
1200 Lincocin Injection 300 mg
U.S. MFGR., DATE OF EXPORT:
Merck for Aldomet, Cogentin and Urecholine;
Upjohn for Lincocin
EXPORTER TO U.S.: Vision Medics PTE. LTD.
246 MacPherson Road, #05-02 Beltime Building,
Singapore, 8/3/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: Vision Medics invoice to
National Business Enterprises specifies shipper as
"Multi-Pharmaceuticals Company, Singapore."

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FDA SAMPLE #: 788469
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252647-3
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 9/12/85
VALUE: $17,800
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 4000 vials Mycifradin Sterile Powder
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: FDA Form 701 and Elmcrest invoice
only documents provided.

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FDA SAMPLE #: 788483
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252657-0
REIMPORTER: Sona Distributors
Miami, Florida
REIMPORTATION DATE: Unknown
VALUE: $19,123
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 216 bottles Ditropan 5 mg Tabs (100's)
120 bottles Enduron 5 mg Tabs (100's)
U.S. MFGR., DATE OF EXPORT: Marion - Ditropan
Abbott - Enduron
EXPORTER TO U.S.: G. Doulatram and Sons
(Hong Kong) Ltd., G.P.O. Box 2321, Hong Kong, 9/14/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Only document is invoice from
G. Doulatram and Sons to Sona.
(2) Invoice has Elmcrest Trading, Ltd. typed at top.

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FDA SAMPLE #: 788484
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-258859-2
REIMPORTER: International Shipping Group
REIMPORTATION DATE: 9/13/85
VALUE: $52,945
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Grand Cayman Island
STATUS: Refused entry - document review only
MEDICATION: Quantities illegible --
Retin-A Cream, Parafon Forte, Tolectin, Protostat, Aci-Jel, Sultrin; Ortho - Dinestrol
U.S. MFGR., DATE OF EXPORT:
Johnson and Johnson (Ortho and McNeil)
EXPORTER TO U.S.: Carimed Ltd.
c/o Miller's Pharmacy, Grand Cayman Island, British West Indies
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Sent to the attention of Ben Ramos.
(2) Invoice is the only document.
(3) See FDA Sample # 574995.

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FDA SAMPLE #: 788485
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-516783-9
REIMPORTER: Trevor F. Maingot
REIMPORTATION DATE: 9/14/85
VALUE: $35,006
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Antigua, British West Indies
STATUS: Released - document review only
MEDICATION: 420 Vibramycin Caps 100 mg 50's
300 Vibramycin Tabs 100 mg 50's
U.S. MFGR., DATE OF EXPORT: Pfizer
EXPORTER TO U.S.: Hutchinson (Antigua) Ltd.
P.O. Box 1048, St. John's, Antigua
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Invoice is the only document.
(2) Hutchinson stationery says, "importers, exporters and manufacturers representatives."

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FDA SAMPLE #: 788488
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-258870-9
REIMPORTER: International Shipping Group
REIMPORTATION DATE: 9/14/85
VALUE: $13,945
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Kingston, Jamaica
STATUS: Refused entry - document review only
MEDICATION: 12 Ovrette Tabs 28's
360 Corgard Tabs 80 mg 100's
15 Corgard Tabs 80 mg 1000's
72 Mycostatin Cream 15 mg
144 Mycostatin Ointment 15 mg
24 Kenalog in Orabase 5 gm
U.S. MFGR., DATE OF EXPORT:
Wyeth - Ovrette;
Squibb - Corgard, Mycostatin, Kenalog
EXPORTER TO U.S.: Portmore Pharmacy, Ltd.
P.O. Box 1266 Kingston 8, Kingston, Jamaica
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: See FDA Sample # 574995.

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FDA SAMPLE #: 788490
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-258876-7
REIMPORTER: Interland Export Company
5554 N.W. 161 Street
Hialeah, Florida 33014
REIMPORTATION DATE: 9/17/85
VALUE: $142,102
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Paramaribo, Surinam
STATUS: Released - document review only
MEDICATION: 3024 Mycostatin Cream 15 mg
18,000 Mycostatin for Suspension 60 cc
14,016 Mycostatin Vaginal Tabs 15's
3024 Prolixin 2.5 mg 50's
4806 Pronestyl Caps 250 mg 100's
U.S. MFGR., DATE OF EXPORT: Squibb
EXPORTER TO U.S.: C. Kersten & Co. N.V.
27 Steenbakkerijstraat, Paramaribo, Surinam
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: Invoice and packaging slip
are the only documents.

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FDA SAMPLE #: 788491
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-516803-2
REIMPORTER: H.L. Moore Drug Exchange
370 John Downey Drive
New Britain, Connecticut 06050
REIMPORTATION DATE: 9/14/85
VALUE: $10,000
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Antigua, British West Indies
STATUS: Released - document review only
MEDICATION: 300 dozen Mycostatin Vaginal
Tabs 30's
U.S. MFGR., DATE OF EXPORT: Squibb
EXPORTER TO U.S.: Government of Antigua and Barbuda, Permanent Mission to the United Nations, 610 5th Avenue, Suite 311, New York, New York 10020, 9/14/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: (1) Exporter of record listed as L.C.R. Agencies, St. Mary's Street, Antigua, West Indies, but invoice is on stationery of the U.N. Mission of the Government of Antigua and Barbuda.
(2) Invoice is the only document in the file.

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FDA SAMPLE #: 788496
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-252669-3
REIMPORTER: Sona Distributors
REIMPORTATION DATE: 9/19/85
VALUE: $52,137
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Detained - document review only
MEDICATION: 1670 bottles Xanax Tabs .25 mg 100's
2060 bottles Xanax Tabls .5 mg 100's
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Invoice is the only document.
(2) Controlled substance?

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FDA SAMPLE #: 788497
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 85-332737-0
REIMPORTER: Modern Wholesale Drug
6601 N.W. 12th Avenue
Ft. Lauderdale, Florida 33309
REIMPORTATION DATE: 9/16/85
VALUE: $469
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: St. Croix, U.S. Virgin Islands
STATUS: Detained - document review only
MEDICATION: Quantities illegible -
Droncit, Droncit Canine, Strongid T, Paramite Vet-Kem,
Gentamicin Sulfate, Prednisolone, Sod, Succinate,
Heparin, Erythromycin Stearate
U.S. MFGR., DATE OF EXPORT: Upjohn, Miles,
Pfizer, Cater-Glogua, Dell, Chelsea
EXPORTER TO U.S.: Duke Eller
P.O. Box 3242, Fredricksteed, St. Croix, Virgin
Islands
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: Invoice is the only document.

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FDA SAMPLE #: 789000
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-216976-5
REIMPORTER: Sona Distributors
2315 N.W. 107th Avenue, S. #20
Miami, Florida 33172
REIMPORTATION DATE: 9/30/85
VALUE: $89,446
UNLOADING PORT: New York or Chicago
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Detained except for Nicobid (released)
MEDICATION: 350 vials Sparine Injection
150 bottles Sparine Tabs
120 bottles Vasodilan Tabs
4000 bottles Nicobid Tabs
800 Tubes Halog Cream
72 bottles Ceclor Caps
U.S. MFGR., DATE OF EXPORT:
Nicobid - USV Pharmaceuticals;
Halog - Squibb;
Ceclor - Eli Lilly;
Sparine - Wyeth;
Vasodilan - Mead Johnson
EXPORTER TO U.S.: Elmcrest Trading,
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: Detained on importer's premises

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FDA SAMPLE #: 789001
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-216975-2
REIMPORTER: Sona Distributors
2315 N.W. 107th Avenue S. #20
Miami, Florida 33172
REIMPORTATION DATE: 9/25/85
VALUE: $63,641
UNLOADING PORT: Chicago or New York
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Released - document review only
MEDICATION: 2400 ampules Bretylol Injection
500 mg 10 ml;
3822 bottles Pavabid Caps 150 mg 100's
U.S. MFGR., DATE OF EXPORT:
Bretylol - American Critical Care
Pavabid - Marion Laboratories
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: Invoice is only document.

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FDA SAMPLE #: 789002
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192228-8
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 10/1/85
VALUE: $21,756
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Detained - document review only
MEDICATION: 600 bottles Megace 40 mg Tabs 100's
360 bottles Enduronyl Tabs 100's
U.S. MFGR., DATE OF EXPORT: Mead Johnson - Megace;
Abbott - Enduronyl
EXPORTER TO U.S.:
G. Doulatram and Sons (Hong Kong) Ltd., G.P.O. Box 2321, Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Orlando FDA/Miami Customs routinely releases goods to Sona custody.
(2) Elmcrest Trading, Ltd. typed at top of invoice.

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FDA SAMPLE #: 789003
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192229-1
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 10/1/85
VALUE: $211,613
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Hong Kong
STATUS: Document review only --
Nitro-Bid, Debrox, Gly-Oxide released; Elase detained.
MEDICATION: 7812 bottles Nitro-Bid Caps 2.5 mg 100's
4701 bottles Nitro-Bid Caps 6.5 mg 100's
504 bottles Nitro-Bid Caps 9 mg 100's
13,452 bottles Debrox Drops 15 ml
9574 bottles Gly-Oxide 15 ml
3600 bottles Gly-Oxide 60 ml
1000 tubes Elase ointment 30 gm
U.S. MFGR., DATE OF EXPORT:
Marion - Nitro-Bid, Debrox, Gly-Oxide;
Parke-Davis - Elase
EXPORTER TO U.S.: Elmcrest Trading, Ltd.
Hong Kong
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Returned to U.S. by ocean freight.
(2) Invoice is only document.

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FDA SAMPLE #: 789048
FDA DISTRICT: Orlando, Florida
CUSTOMS ENTRY #: 86-192252-1
REIMPORTER: Sona Distributors
8035 N.W. 60th Street
Miami, Florida 33166
REIMPORTATION DATE: 10/8/85
VALUE: $9761
UNLOADING PORT: Miami, Florida
ENTRY PORT: Miami, Florida
EXPORT PORT: Singapore
STATUS: Detained - document review only
MEDICATION: 4700 boxes Naturacil Chewables
U.S. MFGR., DATE OF EXPORT: Mead Johnson
EXPORTER TO U.S.: Satim Pharmacare,
Singapore
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) Returned to U.S. by ocean freight.
(2) Over-the-counter products.
(3) Invoice is only document.

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FDA SAMPLE #: 790502
FDA DISTRICT: New York
CUSTOMS ENTRY #: 86-114326-1
REIMPORTER: MWM Chemical Corporation
270 Madison Avenue
New York, New York 10016
REIMPORTATION DATE: 9/30/85
VALUE: $17,700
UNLOADING PORT: JFK Airport, New York
ENTRY PORT: New York
EXPORT PORT: Hamburg, West Germany
STATUS: Released - document review only
MEDICATION: 30 kgs. net Hydrocortisone
Base Micro USP
U.S. MFGR., DATE OF EXPORT: Upjohn
EXPORTER TO U.S.: APC Trading GmbH
Papenstrasse 3Z, D-2000 Hamburg 76, West Germany
OTHER FOREIGN HANDLERS, RECEIPT DATES: Unknown
NOTES: (1) An invoice from APC to MWM
is the only document provided. Letterhead says APC
(Additives, Chemicals, Pharmaceuticals).
(2) FDA Computer print out lists Upjohn as
manufacturer, but PDR says Organon. See note 1 on FDA
Sample # 646471

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FDA SAMPLE #: 860023
FDA DISTRICT: Buffalo, New York
CUSTOMS ENTRY #: 548792
REIMPORTER: F.W. Meyers and Company, Inc.
69 Delaware Avenue, NUE
Buffalo, New York 14202
REIMPORTATION DATE: 11/15/85
VALUE: $19,892
UNLOADING PORT: Jersey City, New Jersey
ENTRY PORT: Lewiston, New York
EXPORT PORT: Toronto, Canada
STATUS: Detained - document sample only
MEDICATION: 43 200 lb drums of
Super Wernet's Powder (not listed in PDR)
U.S. MFGR., DATE OF EXPORT: Manufacturer missing,
8/11/85
EXPORTER TO U.S.: Block Drug Co. (Canada) Ltd.
36 Northline Road, Toronto, Ontario
OTHER FOREIGN HANDLERS, RECEIPT DATES:
NOTES: Imported "for the account of"
Block Drug Company, Inc., 257 Cornelison Avenue,
Jersey City, New Jersey.

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FDA SAMPLE #: 860278-85
FDA DISTRICT: Buffalo, New York
CUSTOMS ENTRY #: Missing
REIMPORTER: Westhampton Group, Inc.
8505 Washington Boulevard
Culver City, California 90230
REIMPORTATION DATE: 1/15/86
VALUE: $560,035
UNLOADING PORT: Culver City, California
ENTRY PORT: Champlain, New York
EXPORT PORT: Montreal, Canada
STATUS: Detained - document sample only
MEDICATION: 78,768 units Visine 1/2 fl. oz.
68,472 units Visine AC 1/2 fl. oz.
44,604 units Ben Gay Greaseless 1.25 oz.
23,652 units Ben Gay Greaseless 3.0 oz.
17,610 units Ben Gay Regular 5.0 oz.
44,604 units Ben Gay Regular 1.25 oz.
23,652 units Ben Gay Regular 3.0 oz.
46,188 units Ben Gay Children's 1.125 oz.
58,824 units Visine .75 oz.
43,056 units Visine 1.0 oz.
U.S. MFGR., DATE OF EXPORT: Pfizer,
date not available
EXPORTER TO U.S.: Chronometer Time and Medical
Postfach 183 FL 9490, Geneva, Switzerland, 11/30/85
OTHER FOREIGN HANDLERS, RECEIPT DATES:
Morflot Freightliners, Inc., 500 Place D'Armes, Suite 2460, Montreal, P.Q. Canada H24 2WA, 10/28/85 & 10/29/85
NOTES: (1) "Except for the three related sample numbers noted above, this importation may proceed without FDA examination ..." This permission signed by Russell Thompson on 1/17/86, two days after goods arrived in Champlain.
(2) Leslie Steinmetz, President, Westhampton Group, says goods purchased "FOB Montreal," but invoice made in Geneva.
(3) Alternate Chronometer Time and Medical address: c/o Hunkzer Associates, S.A., 15 Rue de Cendrier, P.O. Box 449, CH-1211 Geneva. Administrator - Dr. Mo Beck.
(4) Initial Pfizer shipment to Montreal included 142,464 units of Desitin not subsequently included in FDA sample records although Westhampton Group also

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appears to have reimported it through F.W. Meyers (Brokers) from Chronometer Time and Medical.
(5) Reshipped by ocean freight from Rotterdam to Montreal aboard BALT Canada Line, 5 Mezhevoi Canal, Leningrad 198035, USSR.
(6) S. Varma, Director of CTM, A.G. declared on 11/30/85 that goods were exported from U.S. from the Port of Parsipanny via Montreal on or about 11/15/85.
(7) Report by Russell Thompson (FDA) 1/15/86 stated the reason for return of the goods "resold to U.S. consignee because of low demand because of strength of U.S. dollar."

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